IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF TENNESSEE

AT CHATTANOOGA

UNITED STATES OF AMERICA, Plaintiff, -versus- JERRY WAYNE WILKERSON, MICHAEL CHATFIELD, KASEY NICHOLSON, BILLY HINDMON and JAYSON MONTGOMERY, Defendants.	CR-1-18-11

Chattanooga, Tennessee
November 13, 2019

BEFORE: THE HONORABLE HARRY S. MATTICE, JR.,
UNITED STATES DISTRICT JUDGE

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BENCH TRIAL

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THE COURT: All right. Welcome back, everyone. Are there any matters we need to take up before we call the first witness?

MR. PIPER: Briefly, Your Honor.

THE COURT: Come to the podium.

MR. PIPER: Brandon Chatfield testified last week, Your Honor may recall, Mr. Clark cross-examined him as to his prescriptions, and we neglected -- we showed them to him and we neglected to move them into evidence as Exhibit 109.

THE COURT: Any objection? Admitted.

(Government's Exhibit 109 was received into evidence.)

MR. PIPER: Thank you.

THE COURT: All right. All right. Who's going to call the next witness?

Mr. Thomas.

MR. THOMAS: Thank you, Your Honor. Mark Thomas on behalf of Wayne Wilkerson. We have one witness today, an expert, Mr. Mark Newkirk. I'll have a very, very brief opening, Your Honor. He's a Pharm.D, Doctor of Pharmacy. He specializes in compounding pharmacy compliance and auditing.

THE COURT: Okay.

MR. THOMAS: He has literally been on thousands of audits, that's pretty much his job to make determinations as to discrepancies in claims --

THE COURT: Okay.

MR. THOMAS: -- payments being made and payments being requested by pharmacies to payors to include Tricare and commercial PBMs as to whether or not it is compliant with provisions of the payment or not compliant with provisions of payment. We will also be utilizing him, Your Honor, as a -- he is certainly an expert. We will also be utilizing him to respond to the materiality witnesses that the government has offered both on behalf of CVS and the Tricare program.

THE COURT: Let's talk about materiality in the, in the instance of, well, in this case, health care insurance fraud case. Materiality in this sense, you correct me if I'm wrong, deals with -- in other words, in order for a misrepresentation either an active misrepresentation or a failure to disclose, in order for it to constitute actionable fraud, it has to be something that would have likely changed the decision-maker's decision. Right?

MR. THOMAS: Yes, sir. Had the payor known.

THE COURT: Had the payor known.

MR. THOMAS: They would have said, I would not have paid that claim.

THE COURT: Okay. All right. Okay. All right. Why don't you call your witness.

MR. THOMAS: Thank you, Your Honor.

(Brief pause.)

THE COURT: What's the witness' name again?

MR. PIPER: Mark Newkirk, Your Honor.

THE COURT: Newkirk.

Mr. Newkirk, come on up here to the witness stand. Right up here. And I'm going to ask you to step up, take the step up into the stand, but before you sit down, if you would, stop, raise your right hand, and face Ms. Capetz, she'll swear you in.

(Witness sworn.)

THE COURT: Have a seat. If you'd like some water, there should be some there in the pitcher.

THE WITNESS: Okay.

THE COURT: Make yourself comfortable. I'm going to ask that you speak into the microphone. And once he's settled, you can proceed, Mr. Thomas.

MR. THOMAS: Thank you, Your Honor.

MARK NEWKIRK,

called as a witness at the instance of the Defendant Wilkerson, being first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. THOMAS:

Q Good morning, sir.

A Good morning.

Q Are you settled in there?

A As much as I can be, yes. Thank you.
Q All right. And you can see the screen in front of you there. Correct?
A Yes, I can. Thanks.
Q Please state your name for the record.
A Mark Robert Newkirk.
Q And, Mr. Newkirk, please tell the Court, what do you do for a living.
A Currently, I am a -- I work for a company called Pharmacy Compliance Consulting, and we work with pharmacies, independent pharmacies for the most part around the country and we consult on compliance issues with pharmacy benefit managers. We help with audits and appeals, you know, basically, their interactions with the PBMs.
Q And, Mr. Newkirk, how long have you been doing that?
A This company formed two years ago in January is when I joined. I've been in the pharmaceutical industry for, you know, 20 plus years though overall.
Q And, Mr. Newkirk, does this appear to be a copy of your current CV?
A Correct, yes.
Q That appears to be a copy of the CV that you provided to me. Correct?
A Yes, it is.
MR. THOMAS: I'd offer, for the record, what's

Defendant's Exhibit 101.

THE COURT: Any objection to admission?

MR. CLARK: No, sir.

THE COURT: Admitted.

(Defendant Wilkerson's Exhibit 101 was received into evidence.)

MR. THOMAS: Thank you, Your Honor.

BY MR. THOMAS:

Q And, Mr. Newkirk, what did you do prior to your current position?

A It might be probably easiest to maybe give a little chronological --

Q Please.

A -- explanation of my background in pharmaceuticals. I started -- I have a Bachelor of Science in business administration degree. And after getting this degree in 1989 or so, I, you know, unfortunately, had testicular cancer and became interested in pharmaceutics through that process.

THE COURT: Uh-huh.

THE WITNESS: And I moved to -- I grew up near Cincinnati, Ohio and I went to Cincinnati, Ohio and got a job at a high volume independent pharmacy called Group Health Associates.

THE COURT: High -- what kind of pharmacy?

THE WITNESS: A high volume independent -- they

processed many, many claims.

THE COURT: Okay.

THE WITNESS: Five hundred, they averaged 500 prescriptions a day.

THE COURT: Okay.

THE WITNESS: Back then in the early '90s that's a lot because of the systems weren't the greatest.

THE COURT: Yeah.

THE WITNESS: This was my first hands on experience. And what I was doing concurrently was taking the -- I had a business degree, but I didn't have the science background, so I was taking the science courses, the biology, the physics, statistics in order to qualify to go to pharmacy school. And, you know, two, three years later, I applied to a couple of pharmacy schools and couldn't get in and started putting out resumes to, you know, look for, you know, a better income.

THE COURT: Yeah.

THE WITNESS: And Medco, large PBM in New Jersey hired me. They were one of the largest at the time. And they hired me to be a pharmacy auditor. And so, for 13 years, the next 13 years, I worked as a pharmacy auditor, traveling mostly in the midwest, but as far as Seattle to audit independent pharmacies, chain stores, long term care, hospitals, anybody who billed a claim to Medco, I could walk in the door and audit.

THE COURT: Okay.

THE WITNESS: It was --

THE COURT: I mean, that was part of the pharmacy's contract with Medco, that you, they could send people like you out to check on what --

THE WITNESS: Correct. If you have a contract with a PBM, you know, as long as they follow the procedures, send you a letter, hey, we're going to come in, we're going to audit on this date, please be ready for us.

THE COURT: Yeah. All right. All right.

THE WITNESS: And so, I did that for 13 years. But the ninth year in, I was -- by then, we had moved to Pittsburgh, Pennsylvania, my wife and I. That's where she grew up so that decision was obviously that we move to Pittsburgh. I was in a chain store, Giant Eagle Pharmacy, and the district manager because district managers would always come and do the audit with us, and she asked me why aren't you in Duquesne University weekend program for pharmacy school. And I went, you know, who has a weekend program, are you out of your mind. So, I looked at it. I had already done all of the prereqs. I applied. I got in surprisingly. So, for the next really three-and-a-half years, I went to school on the weekends, Saturday, Sunday, eight to six, year round, while still working at Medco.

THE COURT: Okay. Did you go physically to Iowa or

did you do it on line?

THE WITNESS: No. Physically at the University.

THE COURT: Okay. You would fly back and forth from Pittsburgh?

MR. PIPER: Duquesne is in Pittsburgh, I think.

THE WITNESS: Yes, Duquesne is in Pittsburgh.

MR. PIPER: Yes.

THE COURT: I thought you said Iowa. Okay. I got my geography wrong. Duquesne is located in Pittsburgh.

THE WITNESS: Yeah. Five -- I would not -- oh, gosh.

THE COURT: Thanks for the geography lesson.

THE WITNESS: I couldn't imagine doing that. It was hard enough driving five miles down. But we'd have a midterm every Saturday morning. And it was just, you know, wife, two small kids, working full-time --

THE COURT: You were going to school on the weekend?

THE WITNESS: Got through the program. Excuse me?

THE COURT: Going to school on the weekend?

THE WITNESS: Yes.

THE COURT: You were a pretty busy guy during this period?

THE WITNESS: It was a nightmare. Hardest thing I've ever done, including, you know, cancer.

THE COURT: Right.

THE WITNESS: Got through the program. Graduated. I had to quit Medco at that point and do my rotations. And I got my rotations done. Took the boards. Passed the boards. Medco hired me in the end as a pharmacist at their mail order facility in Pittsburgh. I worked for them for two-and-a-half years, stepped up to a manager, had 50, 55 pharmacists under me, 14 techs. Then Express Scripts bought Medco. And I lasted about nine months or so. And it was a pretty poor work environment.

THE COURT: Yeah.

THE WITNESS: I had a Pharm.D, which I consider a golden degree. Left. Joined Freedom Pharmaceuticals, which is in Tulsa, Oklahoma, but I worked out of my house in Pittsburgh, consulted, worked for them teaching a billing class on compound billing. How to properly bill, if possible, according to all of the manuals. And, you know, all of the rules and how the manuals are different. And then we had client pharmacies all over the country.

THE COURT: Is that a subspecialty within, you know, the pharmacy profession, I mean, compounding, as opposed to, compounding as opposed to, I guess, what is it --

THE WITNESS: Traditional retail pharmacy?

THE COURT: Yeah, labeled drug that's produced by who knows.

THE WITNESS: Any pharmacist or any pharmacy is

capable of compounding.

THE COURT: That's what you're trained to do. Right? Put together --

THE WITNESS: You are definitely trained to be able to compound, but to have the expertise to do compounding, you know, taking two tubes and squirting together and mixing and putting it into a container, yes, anybody can do that.

THE COURT: Yeah.

THE WITNESS: But taking bulk chemicals, mixing them together, doing it properly, it's a higher level.

THE COURT: You need to do it right?

THE WITNESS: You need to do it right. And you need to have some training, some experience. You have to have the right equipment. You have to have the right lab. Back early when I audited for Medco, I would go in and they would just have a table and there are bulk chemicals, hormones, they are just mixing, no mask, no gown. And I didn't know any better because I was young. I wouldn't walk in the door of a facility like that nowadays.

THE COURT: Yeah.

THE WITNESS: But for the most part they don't exist anymore. They have hoods. They have separate rooms. There is a lot of regulation on how you compound and it's expensive.

THE COURT: All right. Go ahead.

THE WITNESS: I think that gets us --

THE COURT: So that's --

THE WITNESS: -- pretty close up to today. And then after Freedom Pharmaceuticals, I moved on. I formed a company to go after unapproved drugs that are processing and paying out there. And, you know, I'm still pursuing that. But what's, what's, you know, how I'm earning a living right now is in the consulting world with mostly independent pharmacies, small chains.

THE COURT: As I understand what you're describing to me, you've sort of switched sides, and that's very common, I mean, particularly in the legal profession. You used to be an auditor going in there to decide whether we're going to pay or deny this claim by this particular pharmacy, and, now, you're assisting pharmacies, if the auditors come up and say, hey, we're going to deny this claim, working with presumably the PBM, and, wait a minute, maybe I don't think you understand what we got here.

THE WITNESS: Switching sides. Yeah, you know, in a classic sense, yes. But it's the same rule book.

THE COURT: Same what?

THE WITNESS: It's the same rule books.

THE COURT: Yeah.

THE WITNESS: I just know the rule books. Typically, I'll research state law, as well as I can. I'm not an attorney.

THE COURT: Yeah. Right. Right.

THE WITNESS: But many pharmacies, you know, they don't always fight an audit because they don't know how.

THE COURT: Yeah. Right.

THE WITNESS: And, you know, these manuals are, you know, super thick, they're chalked full of all kind of little things and they'll sit on a shelf and maybe not so critically read. That's where I come in.

THE COURT: I think I understand. Okay.

BY MR. THOMAS:

Q Thank you. Mr. Newkirk, let me ask a couple of follow-up questions. You mentioned you were a Pharm.D. Correct?

A Correct.

Q And that's Doctorate in Pharmacy. Correct?

A Right.

Q Is that the final degree that you can get as a pharmacist?

A As a pharmacist, yes. I suppose there is maybe a Ph.D., but, yeah, I'm done with school. Thank you.

Q And your background, that includes not just the ESI Medco PBM, you have dealt with the other PBMs as well. Correct?

A Correct. Correct. And, you know, dealing with audits, you deal with, you know, any time you process a claim

as a pharmacy, it could be, you know, one of, you know, maybe 100 or 200 PBMs, but there is four big ones.

THE COURT: What are the four big ones in the United States?

THE WITNESS: Express Scripts, CVS Caremark, Optum, and Prime Therapeutics that's who I view as basically the few. Optum is United Healthcare. United Healthcare used to be with Medco, and they got tired of, my opinion, they got tired of paying Medco so they just bought their own PBM and brought it in house so they could --

THE COURT: I see. Okay.

BY MR. THOMAS:

Q And, Mr. Newkirk, or is it Dr. Newkirk?

A Mr. Newkirk is fine.

Q Mr. Newkirk, do you have experience also in governmental payors, Medicare or Medicaid or Tricare?

A Yes. Yes. The processing of claims to Medicare Part D, and, you know, the formulary design and Tricare, and the Tricare compound benefit, yes, I do.

Q Okay. Does Tricare utilize a pharmacy benefit manager?

A They do. Currently and at that time, it was Express Scripts.

Q Okay. And is that the same Express Scripts that also handles commercial PBM work?

A Yes. Yes.
Q So, the PBM just works underneath a contract. Correct? Just depends upon --
A Correct.
Q -- whether it's government or private?
A PBMs will have multiple plan sponsors, three, 4,000, you know, on average, the large ones. But including they're going to, you know, every PBM wants to also have Medicare Part D because that's the largest prescription, you know, benefit group in the country.
THE COURT: In the world, I guess?
THE WITNESS: They're the largest purchaser for, you know, my understanding of prescription drugs in the world.
THE COURT: Yeah. And they don't -- and Medicare Part D doesn't have a pharmacy benefit manager, I mean, they handle it in house with government employees, I guess?
THE WITNESS: I think almost the exact opposite.
THE COURT: Oh, okay.
THE WITNESS: They outsource to all of the PBMs out there the Medicare Part D administration, they hire --
THE COURT: And they become in that sense a government contractor, the PBM, they contract with HHS?
THE WITNESS: Correct. They work together on the formulation, just like a regular plan sponsor.
THE COURT: Okay. Good. All right. Thanks.

BY MR. THOMAS:

Q Mr. Newkirk, do you go on site, did you go on site when you were auditing pharmacies?

A Yes. Extensively. I was a field auditor. There is typically in an insurance company or PBM, there are field auditors and in-house auditors. In-house auditors will send out something like a desktop audit, which is a fax, here's two prescriptions, please send us the information on this and respond. Field auditors, you know, go out and walk in, physically walk in the door. And you'll have -- we used to have, you know, I've been doing this for so long, when we originally started, we didn't have laptops so they would mail out a box of prescriptions and we'd go back six, eight weeks worth of claims. When we got laptops, we extended that to two years. So, it's two years worth of data is the typical look back.

Q And the pharmacies that you audited, was that within a state, was it regional, was it nationwide, what was the geographic scope?

A It was nationwide. Mostly I was based, you know, when I started I lived in Cincinnati. And then we moved to Dayton for my wife to finish up her registered dietician and then we moved to Pittsburgh. But I would travel all through the midwest as far as, you know, California and Seattle. If we had a client who called, we were on the plane.

THE COURT: You used a term about the audits, and we've talked a lot in this trial about the so-called look back method. And we've had at least one witness on the stand, I think, from CVS Caremark. And, you know, and he described, as I recall, what sounded like a very sophisticated software program whereby CVS Caremark to the extent possible or theoretically possible to monitor in very broad terms claims in realtime. But it sounded, you know, yeah, we can do a little bit of that. Here's what it sounded like to me. We can do a little bit of that using artificial intelligence through computers and so forth, but, realistically, given the volume of scripts that are being submitted in the United States in 2019, I mean, it almost has to be primarily a look back system. Is that -- that was my understanding of his testimony.

THE WITNESS: Yes and no. I think that a lot of times what PBMs will do, what we did at Medco is we would build programs to look at outliers, so if you have an inhaler --

THE COURT: Using what I'm referring to as artificial intelligence, the computer is programmed, okay, look for these markers?

THE WITNESS: Right.

THE COURT: And in our experience sometimes at least indicate there is something amiss.

THE WITNESS: A good example would like an inhaler, an inhaler is 17 grams, many of them. So if they entered a quantity of whatever 17 times 17 is, you know, 134 --

THE COURT: Okay.

THE WITNESS: -- you would look for that, because instead of just entering it as a quantity of one, they entered, you know, quantity one then their --

THE COURT: Nobody needs 17 inhalers at one time?

THE WITNESS: Exactly. And it was a mistake. And they should be able to run reports and pick that up on a daily basis. But for the most part, it is, it is a retrospective look back at the claims data in order to analyze it.

THE COURT: Okay. Just because, I mean, you know, a physician's decision to write a script is, while it sounds simple, I mean, basically, it involves, you know, an incredibly complex set of variables to make the final decision?

THE WITNESS: I would completely wholeheartedly agree.

THE COURT: Okay. All right. Go ahead.

MR. THOMAS: Thank you, Your Honor.

BY MR. THOMAS:

Q Mr. Newkirk, could you give the Court any idea how many pharmacies you've been in professionally?

A It's thousands. I look at, you know, when I worked

for Medco, we averaged, we tried to do 10 audits a week. And, you know, 50 weeks a year for 13 years is over 6,000 pharmacies, you know, a lot of those are repeats, but in every pharmacy we're looking at 100 to, you know, 150 at least individual prescriptions. So, I've reviewed many, many, many prescriptions.

Q Any rough idea for the Court how many audits you participated in at those pharmacies?

A Well, they were all audits, you know, from that perspective. Right. The consulting side and working for Freedom --

THE COURT: Thousands --

THE WITNESS: Thousands.

THE COURT: Tens of thousands?

THE WITNESS: Thousands of audits.

THE COURT: Okay.

BY MR. THOMAS:

Q Briefly for the Court, Mr. Newkirk, what do you do in an audit, in general, what do you look at?

A You have data when you walk into a store and you have all of the, you basically have a retrospective look back at the claims data. And the night before I would typically target what claims I wanted to review. So, if it's a busy store, I might have, you know, 30,000 claims. I need to run some filters and look for outliers, you know, anything over

thousand dollars, I'd probably look at. Anything with a dispense as written code where the doctor indicated you could only dispense the brand. I'd probably look at it and make sure that the doctor actually did it. If there is a quantity change, you know, prescription they got 30, 30, 30, then they got a refill for 90, I'm going to look at that prescription and say, well, what did they write for because if they only wrote for 30, I'm going to pull back 60 on the audit.

Q So, is it fair to come to the conclusion that you go into the audit, you've got a set of standards, you review the prescriptions, compare them to the standards and make determinations as to what's discrepant and not. Is that fair?

A Yes. According to, you know, I could make a discrepancy according to the rules of the PBM, you know, Medco. So, if you're allowed to increase the quantity, I probably wouldn't look at the because if I can't make it a discrepancy, there is no real reason to look at.

Q And that's how you find discrepancies. Correct?

A Correct.

Q The preset, prior standardized terms for the PBM and to determine whether the pharmacy complied with that or not?

A Correct.

Q Is that done on all of the claims all at once or is it done on a claim by claim basis?

A It's done on a claim by claim basis and only the

claims you choose to look at. You know, you can't -- I can't go in and review 30,000 claims in a couple of hours. It's just -- it's just -- you can't.

Q Is there a standardized format like a set of discrepancy codes, some kind of a legend that you utilize to find out whether any given claim has no discrepancies or one or 10?

A Well, every PBM has their own set of discrepancy guidelines and what they consider and what they'll call, you know, if you, if it's written for a quantity of 90 and you decrease it to 30, and, you know, it's commonly called a cut quantity. But one PBM may call it something different.

Q Those are pretty set. Correct? You don't walk in the door and then start to, you know, kind of determine your own discrepancy codes, your own legend, right, it's preset? Correct?

A Correct. You cannot just, you know, I've never seen where you just make up a new discrepancy at the time.

THE COURT: Can I stop and ask you? You know, in another lifetime, somebody with my name who was much, much younger than I am now, was a financial auditor, okay, for a big accounting firm. And what you're describing is a process that you go in and look for what I'm going to refer to as outliers, you know, the night before you look for, for outliers. When I was a financial auditor, we did some of

that, and, obviously, but more prominently at least, and I was a very low level accountant, I mean, we had what was considered back then to be very, very sophisticated statistical analysis where we would conduct a random audit of certain transactions to see -- do you do that as well as the outliers or not?

THE WITNESS: No.

THE COURT: Okay.

THE WITNESS: Not so much --

THE COURT: You're not doing random selection --

THE WITNESS: Absolutely not. And there is a reason.

THE COURT: Tell me why. Yeah. Tell me why.

THE WITNESS: Because if you look at pharmacy data as a whole and you bill 1,000 claims and you just randomly pick five. Chances are I'm going to look, you know, five out of the five of those may be for, you know, a very cheap hydrochlorothiazide --

THE COURT: You know, if somebody wants that, we're going to give it to them, you know, hopefully their physician made them --

THE WITNESS: Thirty of them are 30 cents. You know, I can audit that all day long, it's a waste of time.

THE COURT: That's not where the money is?

THE WITNESS: Absolutely not.

THE COURT: Now, let me ask you something else. And I've been wondering about that. Is that what you do, do you follow the money? I mean, now that's what the IRS does when they audit someone, okay, yeah, we're not going to fool with a few thousand bucks, we're going to see who's committing --

THE WITNESS: Right.

THE COURT: -- hundreds of thousands or millions in tax fraud, because we want the money. Is that what you do?

THE WITNESS: That's exactly what we did.

THE COURT: Okay. All right. Good. All right. Go ahead. Yeah.

MR. THOMAS: Thank you, Your Honor.

BY MR. THOMAS:

Q Mr. Newkirk, you were an auditor you said for Medco/ESI for 13 years?

A For Medco. I was only an auditor for Medco.

Q Then what other auditing experience do you have other than those 13 years?

A Basically, working with client pharmacies around the country with both Freedom Pharmaceuticals and our compliance company.

Q So, how many years total?

A Close to 20.

Q Twenty. Can you guesstimate how many pharmacy audits you've been in on 20 years, is it one a week or one a

day --
A Well, you know, thousands with Medco. And then, you know, we have pharmacy clients around the country, you know. The consulting company we have right now, we have around 130 clients, you know, from California to the Bronx down to Florida. Freedom Pharmaceuticals, we had client pharmacies all over the country.
Q So, 20 years could literally be more than 100,000 audits?
A That I've had my hands into. I don't know if it's quite, that's --
Q Tens of thousands?
A Yes.
Q Tens of thousands?
A 100,000 audits seems like an awful lot.
Q That includes compounding. Correct?
A Very much so. Very much so.
Q And you had mentioned what compounding is, you know, how it differs from non-compounding. Are there any other audit criteria that you specify, that you look at that makes compound pharmacy auditing different than other types of pharmacy auditing?
A Well, compound auditing is when I looked at compounds, you know, it was, for us, back then, it was a different computer system. If I can, you know, I think you

might want to understand, you know, an important date in the compounding arena was 2011.

THE COURT: What happened then?

THE WITNESS: So, prior to 2011, when you billed a compound to an insurance company you could only transmit one drug, one NDC, National Drug Code. And when we audited, the pharmacy would set in the computer system that it was a compound. Compound? Yes. And it would transmit over to us. But they could only transmit one NDC. And depending upon the price of that NDC, the AWP, the average wholesale price, that's how that would reimburse.

THE COURT: Okay. Now, let me see, make sure. Drug, DNC, drug what?

THE WITNESS: AWP. NDC, National Drug Code, is the identifier that identifies the drug.

THE COURT: Okay. All right. Now, let's just -- we've been talking a lot in this trial talking about Lipitor. Okay?

THE WITNESS: Okay.

THE COURT: So, Lipitor has --

THE WITNESS: NDC.

THE COURT: NDC.

THE WITNESS: National Drug Code. Right.

THE COURT: Now, Lipitor, I mean, has perhaps, I don't know, one active ingredient, but necessarily it's got,

it's a compound because it's got binders or whatever.

THE WITNESS: It's -- no, it's not a compound.

THE COURT: Okay.

THE WITNESS: So, Lipitor when it's approved by the FDA, goes through the FDA approval process. And the way they put the active chemical ingredient in it, and it can have all of the binders and fillers and coating --

THE COURT: We're to ignore all of those?

THE WITNESS: You're going to ignore all of those because it's not compounded, it's a finished drug.

THE COURT: Okay.

THE WITNESS: When you -- back when you could only bill one NDC, this is what, in essence, helped control compound billing. Because if you're billing one drug and the AWP, the price of it is a dollar a gram and you bill, you make a compound, it's 100 grams. And you bill $140 for that, it's only, the max it can pay is $100. So --

THE COURT: Okay. You know, and, I mean, I don't want to get too far off of the beaten path here, but I'm trying to understand compounding. Okay. When Pfizer was developing Lipitor. Okay.

THE WITNESS: Uh-huh.

THE COURT: Presumably its scientists didn't discover a brand new previously unknown chemical because there is nothing new under the sun, I mean, you know. I mean, it

existed from time immemorial. What scientists at Pfizer did was put together certain pre-existing chemicals and found one that, you know, what I'm going to call a combination or a compound that works. And they said, aha, you know, we're going, we're going to submit this, go through the regulatory process everything and then once we get approval, we're going to call it Lipitor.

THE WITNESS: Correct.

THE COURT: And we're all going to get rich. Now, what's different from what the Pfizer scientist did and what a compounding pharmacy did --

THE WITNESS: Okay.

THE COURT: -- does?

THE WITNESS: So, a compounding pharmacy is going to take multiple ingredients and combine them together.

THE COURT: Right.

THE WITNESS: And they do not -- they're not required to go through the FDA approval process in order to do that and dispense it.

THE COURT: Not even, not even when, I mean, even the individual ingredients don't have to go through the --

THE WITNESS: Correct. So, many compounds use bulk chemicals. No bulk chemical is FDA approved. Bulk chemicals are components of FDA approved drugs. You could take six different bulk chemicals and a base and combine them all

together and --

THE COURT: That seems like to me, you know, just from a public health standpoint that seems like a big loophole to me because, wait a minute, I count on the government through the FDA to tell me is what I'm going to put in my mouth going to kill me. Okay. That's what, as a citizen, that's what I think, you know. And I guess I've always thought, that, you know, if I can buy this at a grocery store or drugstore or somewhere else, somebody somewhere has decided, somebody with authority and training, that's not going to kill you probably.

THE WITNESS: That would be the physician. And compounding has been going on since the time of pharmacy. Compounding is prior to Merck. It's prior to Lipitor.

THE COURT: There were drug stores long before we had an FDA and stuff like that.

THE WITNESS: Correct. And I don't, I absolutely don't view it as a loophole, you know. Statutorily, it's allowed. You're allowed to compound multiple ingredients per a prescriber and, you know, put it together. And it's exempt from going through the FDA approval process.

THE COURT: Okay. All right. Go ahead.

BY MR. THOMAS:

Q Thank you, Mr. Newkirk. So, are we correct in understanding that the control mechanism, the gatekeeper for

compounding is the physician who sees the patient and writes the prescription. Correct?

A Correct. You need a prescription in order to, you know, fill it.

Q And is there an interchange, a colloquy, a back and forth between the doctor who writes the prescription and the pharmacist who fills the compound?

A There absolutely can be, yes.

Q Because it's unique. Correct? It's a, it is a unique compilation of drugs designed for one particular patient?

A Correct.

Q Right. The pharmacies often start out with a preprinted suggested compound pad. Correct?

A Yes, they can. Yes. Absolutely.

Q And that's to assist the doctor. Right?

A Yes. Many times it's to allow for clarity and I think that, you know, compounding is complex. You can have multiple ingredients in a compound. And to me, you know, physicians' handwriting is difficult enough writing one drug, you know. Now, imagine them writing six drugs, six different strengths and the quantities, and then having to interpret that. So, a preprinted prescription pad makes absolute sense when, you know, how I look at it like that.

Q The doctor can change that prescription. Correct?

A Yes. Absolutely. They have, you know, full power to change a strength, if they, if they don't need a chemical in there, or they don't agree or something, they, you know, they can, you know, just cross it out. It's no longer on the prescription.

Q Can the pharmacist change the prescription after the doctor has written it?

A With the physician's permission. You know, they have to -- any time you make a change to a prescription, you need to get back, you know, with a doctor and get authority.

Q Okay. So, we've established that the bulk active ingredients that go into compounds don't have approval, they're not, they're not preapproved by the Food and Drug Administration?

A Correct. Bulk ingredients are not FDA approved, they're components of FDA approved drugs.

Q And to go the Court's question, so how is it that doctors and pharmacies know what active bulk ingredient to choose to go into a compound if they can't go to an FDA approved list? How does that process take place?

A Well, they're writing for the, you know, drug that they want to be utilized in the compound. And many drugs, say Omeprazole is a common drug in compounding you could take, you could order Omeprazole capsules and open them and, you know, use that ingredient to make the compound or you can order a

bulk ingredient, Omeprazole bulk powder, so they are available in multiple ways.

Q And, Mr. Newkirk, could you spell that medication?

A Omeprazole?

Q Yes.

A O-m-e-p-r-a-z-o-l-e.

Q Okay. Let's talk briefly about pricing. Who sets the prices for the bulk ingredients for compounded medication?

A The manufacturer does or whoever the labeler is of the particular drug. They set the price.

Q And is that, is that per compound or per bulk cost go into an average, a nationwide average, to calculate the average wholesale price for that bulk?

A No. The average --

Q How is the AWP calculated?

A They just, the manufacturer selects it.

THE COURT: All right. And the manufacturer of, for instance, you know, an FDA approved drug, a pharmaceutical company, hey, let's call it Pfizer.

THE WITNESS: Pfizer.

THE COURT: Okay. The manufacturer of a compound is going to be the pharmacy that does the compounding. Right?

THE WITNESS: Well, the pharmacy compounds the drug. But the way that the drug ends up being priced is the different AWPs, the average wholesale price of each

ingredient. So, when you transmit a compound claim after 2011, you could bill for up to 25 ingredients. That was the big change. And you would enter each NDC, and the average wholesale price of each one and the quantity, it's a completely 100 percent transparent transaction with the PBM. They have every single ingredient, the quantity, the AWP, it adds all up, and whatever it adds up to, it gets transmitted to the insurance company.

THE COURT: Okay.

BY MR. THOMAS:

Q So, Mr. Newkirk, if I understand your testimony, effective as of 2011, the software change that you had mentioned, up to 25 individual bulk ingredients could be added into a single compound. Right? A single script.

A Correct. Correct.

Q And the pricing would be based upon the manufacturer's AWP, what the manufacturer suggests. Correct?

A Correct.

Q And then it's multiplied by the amount of that compound. Right? Whether it's one grams or 20 grams or 30 grams. Correct?

A Correct.

Q And then once you have a per ingredient total, you total all of the 25. Correct?

A Correct.

Q And that's why each and every compound prescription is unique. Correct?
A Correct.
Q As far as the payment goes, and thank you for that, I'm kind of working on the pharmacy and the manufacturer side, let's jump over to the other side of the industry. So, when that claim goes into a PBM and the PBM receives it, does the PBM reprice any of those bulk ingredients or do they take the manufacturer's AWP?
A They pay according to contract which is going to be based off of AWP. So, if compounds pay at AWP minus 15, you have, you know, the ingredient add up to $1,000 and the contract pays compounds at AWP minus 15, it's going to pay at $850 to the pharmacy.
Q Got it.
A If all of the ingredients are covered.
Q And the PBM sets that AWP based price on a per bulk item basis. Correct?
A Well, per -- not even per bulk, per the compound claim. So, you could have bulk chemicals in there, you could have FDA approved ingredients, tablets, capsules, you could have multiple ingredients in there, basically, if it adds up to $1,000, they are going to pay per contract off of that $1,000.
Q I see. Let me take you back to the software matter

that you had mentioned in 2011. Whose software program was that, was it the pharmacies or was it the PBMs?

A It's the pharmacies had to upgrade their software in order to transmit all of the new data fields and communicate really with the insurance companies.

Q Prior to the software upgrade, how many bulk items could be utilized in one prescription?

A You could -- you could make a compound with as many ingredients as you wanted prior to that upgrade, but you could only transmit one NDC, one drug.

Q So, the software upgrade allowed a transmission of up to 25 NDCs?

A Correct.

Q And what was the impact on the industry of that, if any?

A Growth. Transparency. Pharmacies now instead of, you know, if you billed one NDC and the price of that NDC was ten cents and you billed 100 grams, you couldn't be paid any more than $10. Now, you could take, if you had 10 ingredients, and they all added up to $500, and you billed $500, you could be paid off of that total price now.

Q You mentioned transparency several times. Does that mean that the PBMs could look at the individual claim for each compounded prescription and decide whether or not to pay it?

A Yes. I mean, and it was, when I was an auditor, we

knew it was a compound claim but we only had one drug. So, we had to actually physically audit any compounded drug in order to figure out if it was even ballpark being priced right, we had to do a physical audit.

THE COURT: And that seems like that's a pretty time consuming endeavor?

THE WITNESS: Oh, yes. We could, you know, if I audited --

THE COURT: You can't do a whole lot of those in one day?

THE WITNESS: You cannot. And there is no way we could, you know, review all of the compounded prescriptions in the country. I mean, there weren't nearly as many as compounding pharmacies at that time because of how difficult it was to get paid for compounds, but after 2011, I'd say, you know, it's 100 percent transparent claim. The PBM knows everything that's in there.

THE COURT: Let me -- I really am reluctant, Mr. Thomas, to interrupt your direct examination. And I'm going to let you go back, but can I interrupt?

MR. THOMAS: Yes, Your Honor.

THE COURT: What you're describing to me about compounding. Let's just assume theoretically that there is a compounding pharmacy out there who really just has no concern whatsoever for the efficacy, I mean, they are concerned that

we're not going to kill someone because they're going to get sued for that or something, but no concern for the particular efficacy of the drug and no concern for patient welfare, something like that. We just want to create a compound drug that will generate the most profits, okay, in the health care market. It seems to me that there would be an incentive out there for such, you know, let's just call it amoral, you know, compounding pharmacy, let's decide the ingredients that based upon this, what you call it, average wholesale, AWP --

THE WITNESS: AWP.

THE COURT: -- would yield a compound that is the most expensive. Okay. Let's just assume that for the time being. This is a theoretical question. Follow me.

THE WITNESS: Okay.

THE COURT: And then, you know, got a health care professional to prescribe that. And so, that compounding pharmacy would yield, would reap the profits, you know, of that compound, it seems to me. Follow me through, then let me finish. Okay. Now, from my meager understanding of how economics work. The only check on unlimited profits for that compounding are the forces of supply and demand. In other words, the assumption that, you know, given two equally efficacious drugs, the consumer is always going to choose the less expensive. Okay. That's my understanding of how economics works.

Okay. Now, let me throw in a monkey wrench because I do believe that in a system, in a market economy, a system of supply and demand, insurance can skew the normal economic calculations because of something that we have referred to various times, including moral hazard. In other words, if I'm not paying for it, I don't care what it costs. What's wrong with the sort of analysis that I just sort of went through?

THE WITNESS: It's kind of -- I don't know that there is anything wrong. You've described a free market. And one of the things missing --

THE COURT: I described a free market up to the point that I said, but let's throw in some significant insurance coverage and that has a tendency to, whatever you, skew, distort, whatever term you want to use, the normal mechanisms of a pure free market.

THE WITNESS: Right. Because patients when they walk into the pharmacies are disassociated from the true cost of what a drug is.

THE COURT: Any insurance works that way, I suppose. I mean, presumably, if I have really good homeowners insurance, I have a little bit less incentive to not leave my gas stove on, you know, when I walk out, you know. I mean, we try to guard against that, but, you know.

THE WITNESS: Right.

THE COURT: That's just -- that's the nature of any

insurance.

THE WITNESS: But, you know, most patients when they walk into a pharmacy and they pick up five medications and they pay $80 total in a copay, have no idea if they're walking out of the store with $80 worth of meds, or $25,000 worth of meds.

THE COURT: Okay. All right. Okay. All right. Go ahead. Go ahead.

MR. THOMAS: Thank you, Your Honor.

BY MR. THOMAS:

Q Mr. Newkirk, just to make sure that we all understand, I need to ask a few more follow-up questions regarding pricing. The PBMs pay on a per item and per amount, right, per bulk amount basis for each individual bulk item within a compound prescription. Correct?

A Correct.

Q And that's based upon a discount from average wholesale price. Correct?

A A discount or even in the case of Medco, they paid straight AWP on compounds.

Q And that's based upon contract. Correct?

A Correct.

Q And who's the contract with, is the contract between the PBM and the pharmacy or is the contract between the PBM and the manufacturer?

A Not the manufacturer. The contract is -- there is really two contracts, you know, a pharmacy will have a contract with the PBM and the PBM will have a contract with the insurance company or the plan sponsor and those will lay out the terms.
Q Is there a third contract as well where the pharmacy has a contract with the manufacturer to actually buy the products that they ultimately utilize for the compounding?
A The pharmacy will have a contract -- if you're going to purchase bulk chemicals or drugs from a manufacturer or from a wholesaler, you're going to have to have a contract in order to purchase those. You can't just call up and order drugs without executing a contract. They're going to want to vet you as a pharmacy.
Q Because the pharmacy has got to buy the raw materials from someone. Correct?
A Correct.
Q And I don't mean to oversimplify, but my basic understanding, and I'm not a pharmacist by any means, so keep it simple for me, please, the pharmacies buy low and sell high. Right? They buy at a discount from AWP from a manufacturer or a distributor or a wholesale or repackager, then they do the compounding, and then they send a claim in for the compound that they made, right, they're the professional entity with a license to a PBM with whom they

have a contract and say I just compounded a pharmaceutical for your patient, she is an insured, here is the bill. Right? After 2011, it's all laid out as to exactly everything that's in there. And it is a payment rate, a reimbursement rate based upon some portion of AWP higher than what it is the pharmacy paid. Correct?

A Correct. And you're going to have --

THE COURT: It has to be just, again, free market economics, you know, in the long run, if they're not doing that, they will soon be out of business.

THE WITNESS: Correct. And as a pharmacy, you have a choice if you're buying a drug, there may be 10 different suppliers you could purchase it from. And they could have for the same exact drug, they could have 10 different average wholesale prices.

THE COURT: Okay. Yeah.

BY MR. THOMAS:

Q Am I correct in assuming that the pharmacies do that to make a profit. Correct?

A Absolutely.

Q And I'm assuming that the manufacturers do it to make a profit. Correct? They set the AWP at a rate that allows them to be able to make the drugs in, literally, in their factories and sell it to pharmacies. They make a profit. Right?

A Yes.
Q And I'll get into some questions later about the size of the PBMs and their market value, but to your understanding, PBMs make a profit. Correct?
A They're very profitable.
Q Do you have any awareness of the size of some of the PBMs, let's say CVS Caremark, is it a large company, a small company?
A It's a massive company. I think it's in the top 10 or so of the, you know --
THE COURT: Top 10 --
THE WITNESS: Yeah, largest companies.
BY MR. THOMAS:
Q It's Fortune 5.
A They don't lose money.
MR. THOMAS: Your Honor, at this point, I would like to move Mr. Newkirk as an expert in compound pharmacy compliance.
THE COURT: Any objection to that?
MR. CLARK: No, sir, Your Honor.
THE COURT: Yeah. He's acknowledged his -- yeah.
MR. THOMAS: Thank you, Your Honor.
BY MR. THOMAS:
Q Thank you, Mr. Newkirk, very strong introduction for us. Am I correct in understanding that a pharmacy can't

dispense a compounded medication to a patient without a prescription. Correct?

A Correct. You have to have a prescription.

Q Prescription is written by the, by a physician. Right?

A A physician, nurse practitioner, anybody in a state who has prescribing authority according to the state medical board.

Q A patient can't simply go into a pharmacy or order any kind of medication that requires a prescription. Correct?

A They can go into a pharmacy and request something but the pharmacist is going to have to call their physician to get a prescription. Correct.

Q Because without essentially an order or prescription from a doctor, the pharmacist isn't authorized, correct, to dispense to the patient?

A Except in very limited instances like flu shots, you can do collaborative agreements and you're allowed to dispense flu shots without a prescription.

Q That's probably subject to individual specific state law?

A Correct. Correct.

Q As to what authority a pharmacist has?

A And it's very limited.

Q Under what circumstances would a pharmacist check

back with a physician when presented with a prescription?

A Typically, you know, any time your professional judgment alarms are going off in your head. You have a prescription that is typically dosed once daily, and they wrote it three times daily. So, would that generate a phone call? Perhaps unless they have a long history of taking it three times daily. Anything that's outside of the norms is when a pharmacist would pick up the phone. If they bill it and it gets a reject from the insurance company saying they got it down the road two days ago. So, you're going to call the doctor and especially if it's a controlled medication, hey, they got this, are you aware of this, and you go through the process of --

THE COURT: Let me ask another question. To your knowledge, are either pharmacists or to your knowledge, I know you're not a physician, but physicians, are they trained or are they under some sort of legal or ethical obligation to be concerned about the price of any medication or are they solely trained to worry about, you know, the patient, and, you know, and the medical efficacy of the medication?

THE WITNESS: I would much lean towards the latter. Physicians don't know the pricing of drugs.

THE COURT: Well, I mean, I've had physicians who have no idea, you know, if I've gone back to them and said, wow, that thing you prescribed, and they've said how much does

it cost, so, I mean, you know, yeah.

THE WITNESS: And you're typically paying just a portion of it, the copay. You know, the copays have gone up and up and up and you get more push back from the patients to the physician, but they really have no idea.

THE COURT: All right. Go ahead, Mr. Thomas.

MR. THOMAS: Thank you, Your Honor.

BY MR. THOMAS:

Q And based upon the Court's question, how is it that a pharmacist would know when there is adequate clinical efficacy, medical necessity in order to fill a prescription?

A They wouldn't know. I mean, they --

THE COURT: They rely on the physician?

THE WITNESS: Exactly.

THE COURT: If that script --

THE WITNESS: The physician's purview is, you know, they're required to, you know, per the state board, medical board, determine medical necessity in order to prescribe a prescription.

BY MR. THOMAS:

Q There is a basic requirement, though, under most state licensure laws, correct, that when a clinically unexpected prescription is presented for filling where the pharmacist has a responsibility to not just turn the blind eye, right, and fill the prescription, but to do something,

correct, to contact the doctor. Right?
A Correct. Your initials, as a pharmacist, your initials in the end go on anything.
THE COURT: Yeah. Okay. But is it based -- okay. Wow, this doctor just prescribed a really expensive medicine, does the pharmacist, are the obligations you're describing triggered by that or only by, well, boy, this, wonder if the doctor meant to do this?
THE WITNESS: It's clinical --
THE COURT: Okay.
THE WITNESS: -- 100 percent.
THE COURT: As opposed to economic?
THE WITNESS: The economic part is whether it's --
THE COURT: It is what it is?
THE WITNESS: It's either covered or not. Is it a formulary drug and a copay generated.
BY MR. THOMAS:
Q Because the medicine and the pharmaceutical prescribing is supposed to be in the best interest of the patient clinically. Correct?
A Correct.
Q It shouldn't be about the money. Correct?
A Correct.
Q There are instances where a pharmacist can be authorized to change a prescription that comes in from a

physician. Correct? A compound script. The pharmacist might look at a script and say that to me seems clinically unlikely --

A Yes.

Q -- I'll have to check. Correct?

A Yes. Absolutely. If a compounded, you know, if there is a preprinted pad and it came in and you had never seen the preprinted prescription before and you look at it and there is a particular chemical on there and the strength is excessive, you know, it's typically dosed at one percent and it says five percent, you know. You need to pick up the phone and have a conversation.

THE COURT: Unless that chemical happens to be like arsenic or something like that --

THE WITNESS: Well, yes.

THE COURT: -- you know, let's make sure, you know.

THE WITNESS: Well, that's -- as a pharmacist, you own it. So, if it's going out the door, and you're putting your initials on something and it kills somebody, you know, it's, you know the tech is not in trouble.

THE COURT: Yeah.

BY MR. THOMAS:

Q There are other circumstances, correct, other than clinical suspicion when it is that a pharmacist would be authorized, would be motivated to change a prescription. Say

a patient comes in with a prescription for a particular drug, with their insurance card. Right? And the pharmacist checks and it's not a covered medication underneath the patient's plan. Is the pharmacist, is that pharmacist's hands tied to say to the patient, I know you've got a prescription, I'm assuming it's medically necessary, but, you know, you know, your copay would ordinarily be $25, but this is a $30,000 drug. So, did you bring your checkbook? Does the pharmacist have any authorization to make a change in order to be able to get some kind of equivalent for the patient that the patient has underneath their insurance plan?

A In working with the physician, absolutely. And this happens every day, you know, compounds or non-compounds. If you're trying to fill a drug and it's not formulary coverage, what are you going to do? You're going to pick up the phone and call the physician, hey, this is not covered. And then you're going to start the process of figuring out what is covered in order --

THE COURT: Let me give you a common example in my -- we've talked a lot about Lipitor. Well, now, hey, the patent has expired, I mean, you know, I don't even know, I guess they sell name brand Lipitor still, but, I mean, everybody gets generics.

THE WITNESS: Correct.

THE COURT: Now, what's the deal with that, I mean,

I used to see on scripts, you know, the physician say, generic authorized.

THE WITNESS: Substitution permissible. Correct.

THE COURT: Tell you the truth, does a pharmacist just have, okay, if it's a generic, I have the authority to do this no matter what? How does that work?

THE WITNESS: Most state laws mandate that if they prescribe a brand name drug and there is a generic available you're to change to the generic.

THE COURT: Okay.

THE WITNESS: Absent a physician --

THE COURT: It's a matter of state law?

THE WITNESS: Yeah. If they're demanding brand medically necessary or brand only, then you're going to dispense the brand.

THE COURT: So, just in my personal experience, it seems to happen almost as a matter of course. And you're telling me in most states it does happen?

THE WITNESS: You're going to automatically switch to the generic. But, you know, there are sometimes where the insurance company will, you know, you'll fill the generic, you'll get a reject and it will say you must use the brand.

THE COURT: Yeah.

THE WITNESS: And that's largely because the insurance company is getting a rebate and they're going to

tell the plan sponsor you're saving money, which, you know.

THE COURT: All right. Yeah. Well --

BY MR. THOMAS:

Q And that circumstance is dictated by the payor, correct, the PBM?

A Correct.

Q As to whether to approve or not approve the pharmacists substitution of something that's on the prescription. Correct?

A Right. Well, the PBMs also have rules to substitute, also, you know, theoretically, they want you to do the cheapest drug available.

Q So, even after the doctor writes a prescription, gives it to the pharmacist, right, the doctor can change the prescription, the pharmacist can change the prescription, even the PBM can change the prescription. Is that correct?

A As long as it's authorized by the physician or the prescriber in the end. Any change to a prescription, if you make a change, it must be authorized by the physician.

Q And as long as the physician authorizes it, those changes are not improper. Correct?

A Correct.

Q We talked a little bit about compounded medications preprinted pads. Correct?

A Correct.

Q Who produces the pad, the pharmacy. Correct?
A The pharmacy, or, you know, the physician can create a pad. They can do it in working together. But, you know, typically the, you know, an expert compounding pharmacy is going to create, you know, the prescription pad that makes the most pharmaceutical sense.
Q It's proprietary to that pharmacy, is it not?
A The pharmacy would think it's proprietary, but there is really -- if they're working with a physician, there is nothing to stop a physician from, you know, faxing that off to any pharmacy in the country.
Q But doesn't the pharmacist in charge at the pharmacy sort of utilize their own individual clinical knowledge and experience in terms of setting up a suggested compound for physicians. Isn't that a part of pharmacy marketing?
A Yes.
Q That the pharmacist in charge says you can use any compound pharmacy, you should use ours because we have some kind of a special sauce with our formulations. Correct?
A Well, they could, but, you know, they are going to develop relationships with physicians. And, hopefully, they're comfortable with each other and they know the level of competence of the compounding pharmacy. Not everybody can compound.
Q Right. And that was going to be my very next

question. Not everyone can compound. Correct?

A Very true. If a physician sends a compound with five ingredients over to a RiteAid, they can't do it. They don't have the equipment. They don't have the facility. They probably don't have the expertise or, you know, the experience to do it. Typically, it needs to go to a compounding pharmacy. There is Walgreens had, you know, one out of, I have no idea, 30 Walgreens pharmacies has a very elementary compounding, you know. They're able to do pretty simple compounding, but they don't have a hood or anything.

THE COURT: Is it up to the physicians to know who has compounding abilities or not, because, I mean, the average consumer is just not going to have any idea about that, I think?

THE WITNESS: Well, the average consumer doesn't and the average physician doesn't unless they formed a relationship with a compounding pharmacy or they know the local compounding pharmacies, you know, most cities will have a local.

THE COURT: Is there any regulatory framework or is it just buyer beware, I mean, you know, for a compound?

THE WITNESS: There is -- compounding pharmacies currently, they have to have -- it depends upon the state regulations of, you know, it's called 795 compliance. And it's just a level of competence and cleanliness, you know, on

an elementary scale.

THE COURT: Okay.

BY MR. THOMAS:

Q So, preprinted compounding pads are common for compounding pharmacies. Correct?

A Yes. Very common.

Q That's not in any manner restricted or prohibited by the PBMs, is it?

A During that time, they were not prohibited at all except for Express Scripts, they had a caveat. You couldn't have a controlled drug also preprinted on the compound pad. And if they saw -- if you had Ketamine somewhere written on the pad that was preprinted, it was a full recoupment of anything filled off of that. And, to me, it was, it was a made up rule that they put in their manual, but they enforced it. So, the pharmacies learned of this rule when they faced recoupments and they removed all controlled substances from the preprinted pads.

Q And that's just that one PBM?

A That's just that one PBM that had a rule on preprinted.

Q And any other PBMs did not even have that restriction as to controlled substances on the preprinted pad?

A They did not. And they audited thousands of these preprinted pads.

Q And that was going to be my next question. The PBMs audited these compound pads, did they not, during the time period relevant to this case, 2013 to 2015?
A Yes. And as long as it was a clean claim, you know, as long as the pharmacy filled it correctly, you know, if it's two percent, two percent, two percent of three different chemicals and they filled it correctly, they billed it correctly, it's a clean claim, there is, there was not a lot they could do while, you know, auditing those individual claims.
Q There is not an audit discrepancy code that is reserved for the use of a compounded pad. Correct?
A No, there wasn't.
Q You had stated in response to a couple of my earlier questions that compounding is specialty pharmacy work, not every retail store front pharmacy compounds. Correct?
A Correct.
Q So, given that pharmacies are, compound pharmacies are more rare, I hope I can use that term rare, how do they get their medications to the patients, by mail?
A They can. They can. You know, they can. People can come in traditionally and pick up at the pharmacy. If they're far away, they can absolutely mail to any state as long as they are registered as a non-resident pharmacy in order to ship into that state. But one other thing is that

there is, you know, there is, there could be a contractual prohibition against mailing. Optum out there does not allow retail pharmacies to mail, but for compounding, they pretty much for the most part overlook this during that time period.

Q Does that have to do with the enrollment process, the credentialing process with each individual pharmacy with the PBM as to whether or not they can utilize mail?

A It does. When you go through credentialing you have to classify yourself as a retail pharmacy, a mail order pharmacy, a specialty pharmacy. And if you're a traditional retail pharmacy for the most part with the PBMs you're allowed to mail. And they don't want you mailing over, you know, a high volume, a certain percentage, then they are going to say all right, we need to evaluate whether you're a retail pharmacy or mail order pharmacy and they could say we're going to require you to be a mail order pharmacy, and that changes your rates.

Q I'm sorry. That's controlled by the PBM. Correct?

A Correct.

Q And that's a matter of contract?

A Correct.

Q And many of the PBMs inform the pharmacies, correct, that if we don't specifically authorize you to mail, you can't mail. Correct?

A Correct.

THE COURT: Let me --

MR. THOMAS: I'm sorry, Your Honor.

THE COURT: I'm constantly trying to put this information into my own frame of reference. And let me just ask Mr. Newkirk. Currently, I am enrolled in a pharmaceutical plan through my employer that is administered by CVS Caremark. Okay.

THE WITNESS: Uh-huh.

THE COURT: Now, there is a physical brick and mortar CVS pharmacy, you know, half a mile from my home that I've used for years and years. I know the pharmacist, you know. They know me. We talk and stuff like that. However, for the most part, for some prescriptions which fall in the category I would say, for lack of a better term, maintenance prescriptions, I found that the Caremark mail order pharmacy whereby I can get a 90-day prescription just delivered through the mail to me is more cost effective, but not always, you know. I've really found out sometimes, you know, they tricked me on this one, I need to go to my brick and mortar CVS pharmacy for this particular medication because it's a lot cheaper than through the mail order. So, you know, it seems to me from a personal standpoint to be an endlessly complex, you know, if you're determined to on every purchase get the absolute lowest price, who knows, you know. But I don't know if my experience is common out there as to whether mail order

or I'm not really asking for personal advice here, but I'm just trying to understand how the system works between the mail order side and the brick and mortar side.

THE WITNESS: Well, you have to keep in mind who owns the mail order side, and that's the PBM, CVS Caremark, Express Scripts --

THE COURT: They own both of them?

THE WITNESS: Right. They own both of them. So, I have problems with mail order because you could have a cheaper copay for yourself --

THE COURT: Sure is convenient, by the way.

THE WITNESS: It's convenient. They may set up and just, you know, every 80 days mail you a prescription whether or not you need it.

THE COURT: Need it or not.

THE WITNESS: Need it or not, it's just going to auto ship to you because they set the rules. They're allowed to auto ship it to you. They like to fill prescription by mail order because they make money at mail order.

THE COURT: They need less human beings sitting there in their -- fewer human beings sitting there in whatever the big warehouse is where they send than they do in your neighborhood --

THE WITNESS: It's robotic and they're buying a particular drug by the truckload.

THE COURT: And they don't have to have very -- well, expensive, trained licensed professionals there on site or at least not as many as they do in my neighborhood brick and mortar CVS?

THE WITNESS: I worked at a mail order facility.

THE COURT: Okay.

THE WITNESS: And yes.

THE COURT: Okay. All right.

MR. THOMAS: Thank you, Your Honor.

THE COURT: Go ahead.

BY MR. THOMAS:

Q Thank you, Mr. Newkirk. We talked quite a bit about the pharmaceutical and the medical side. Let's switch a little bit, start talking about the payor side. I want to ask a couple of questions about pricing and formulary. Who makes the decision as to what's a covered drug and what's not a covered drug on any given insurance plan?

A Typically, it's going to be the insurance company and the PBM working together. You know, they're going to develop the formulary. There could be a set, you know, a standard formulary. The larger the company, like General Motors, the more input they're going to have on a formulary and exclusions. You know, the small, little company is going to just basically sign up for, you know, a set formulary for the most part.

Q Does that mean that a larger company would have a more expansive formulary?
A It could be either way.
Q Okay.
A They could have a more expansive or a more restrictive, you know, depending upon how involved they're in, you know, in the formulary management.
Q Who sets the prices for those formularies?
A Well, prices are still -- it's always, it's still based off of average wholesale price set by the manufacturer. And, you know, how the claim pays is determined by the insurance company AWP minus X.
Q For the benefit of the Court, I'd like to ask a couple of questions about the relationship between PBMs and the insurance companies. My rough understanding, and correct me if I'm wrong because it's probably rough, is that PBMs essentially act as a contracted agent for the insurance companies. Is that accurate?
A Yes. I mean, they're hired by the insurance company or the company in order to administer the prescription benefit. I view it as an outsourced, you know what I mean, you hire someone to do this because they're experts and you work with them to develop, you know, the best formulary you can.
Q Is that because the insurance companies have all

different kinds of stuff to be thinking about, right, medical claims, durable medical equipment?

A Correct. Yes.

Q Let me ask some technical payment questions. You've heard of the term pharmaceutical rebate. Correct?

A Correct.

Q What is a pharmaceutical rebate?

A A rebate is an agreement between the manufacturer and typically either the federal government Medicare Part D or a PBM, you know, if a drug processes and there is a rebate, they're going, when that drug processes, they're going to capture that data and then the manufacturer is going to pay the insurance company that rebate amount.

Q So, it's money going the other direction, correct, does that makes sense, that the PBM, right, pays the pharmacy who is also paying the manufacturer?

A Correct.

Q And for some reason, whatever it may be, underneath whatever rebate program it is, the manufacturer starts giving some money back to the payor. Is that correct?

A Correct. Well, it's given back to the insurance company, to the PBM. And then it's either, you know, 100 percent sent back to the insurance company or the plan sponsor.

THE COURT: They could achieve the same thing simply

by across the board lowering their prices, but, you know, well, they could --

THE WITNESS: Yes.

THE COURT: They could, but that would be a meat ax approach, something they would rather have more control over by using a scalpel?

THE WITNESS: I mean, the system is really, I think, a lot of smoke and mirrors and very opaque, the way it's currently designed. And if they could get rid of rebates and lower the price of drugs, yeah, that would be a significant lower price of the drugs and to the consumer.

THE COURT: Yeah.

BY MR. THOMAS:

Q Mr. Newkirk, do the manufacturer rebates have any impact as to PBM decisions as to what drugs to put on a formulary?

A Absolutely.

Q How so?

A You know, take for instance, like the Hepatitis drugs, Hepatitis drugs, you've probably heard, you can, Hepatitis C, you can basically cure Hepatitis C, it's $30,000 a month. There is four or five of these drugs out there. You go through three months trial, it's $90,000, and you can cure it. Fantastic. So you launch a new Hepatitis C drug and you want to get it on the formulary. You're going to be offering,

basically, a rebate in order to get it on to the formulary. And if your pricing is not in line and your rebate isn't significant enough, you're not going to make it on to the formulary, whatever it took to develop it.

THE COURT: Well, that's the free market economy at work. In other words, there used to be only one of these things 30,000 bucks a month and now you've got competitors coming in and over time, presumably, the price will be driven down?

THE WITNESS: Correct.

THE COURT: Okay. That's what I learned in economics 101. Okay.

BY MR. THOMAS:

Q Mr. Newkirk, is it fair to conclude that that's an economic inducement for the PBM to put that drug on the formulary versus some other competing drug?

A Yeah. Absolutely.

Q Does that violate any compliance rules?

A No. This is the way the system has been set up and been, you know, running for decades.

Q Have you heard of the term manufacturer coupon?

A Yes. I'm very familiar with manufacturer's coupons.

Q For the benefit of the Court, what's a manufacturer coupon.

A A manufacturer's coupon is say I'm Pfizer and I have

a drug, and it's a, you know, brand name, it could even be a generic drug nowadays and there is a $100 copay on the claim. Patient can't afford $100 copay, so the pharmacy if they look up that drug, they could do it on line, the doctor could have the copay card, the patient can look it up on line. You can find it.

THE COURT: I've seen that.

THE WITNESS: You process that $100, you know, you send the primary claim to the insurance, comes back you owe $100 copay that must be collected. You then bill that out to the manufacturer's coupon, and it could take that $100 copay down to $20, it could take it down to zero. So, they're basically the manufacturer of the drug is paying the copay for the patient.

BY MR. THOMAS:

Q Do you believe that the payors are aware of these manufacturer's coupons?

A The payors for the most part are not aware because the way the system works is you bill the primary claim, you know, the first claim. You bill the drug. It goes out and gets reimbursed by the PBM, by the insurance company. You bill the secondary claim, which is the copay, and it goes out to the manufacturer, and then comes back.

THE COURT: Well, now, wait a minute. Okay. I mean, they may not be aware of it on each individual

transaction, but they are certainly aware that all they have to do is go on the internet and find, you know, yeah, this is what happens.

THE WITNESS: Well, they know the existence of the copay card. They do not know on individual transactions whether or not --

THE COURT: On individual transactions?

THE WITNESS: Absolutely.

BY MR. THOMAS:

Q So, are manufacturer coupons compliant with applicable rules, regulations?

A Yes. As long as, you know, you follow the rules, you know. There is only a couple of prohibitions on manufacturer's coupons. You can't process them on Medicare Part D claims for example. It's not allowed.

Q Any other prohibitions regarding manufacturer coupons that reduce patient copays?

A Medicare Part D and Tricare are really the ones out there that you're not allowed to process.

Q And is there a Tricare copay?

A Yes and no. Depends upon the member. So, if you're, my understanding --

THE COURT: Not for active duty but --

THE WITNESS: Exactly.

THE COURT: -- could be for dependents?

THE WITNESS: Active duty is a zero dollar copay. Dependents, families, back then, the copay was $17.

BY MR. THOMAS:

Q Let's talk for a couple of minutes about copayments. And correct me if I'm wrong, I'm just laying a little predicate here. That's the patient's financial responsibility underneath their insurance plan --

A Yes.

Q -- for them receiving a prescription from a pharmacy. Correct?

A Correct.

Q And who collects that copayment?

A The pharmacy.

Q And is that a contractual requirement?

A Yes. Typically, it's spelled out that the copays need to be collected and by the manuals.

Q Manuals and probably the provider contract with the pharmacy. Is that accurate?

A Or the contract may or may not spell out, the actual contract, but the contract will reference the pharmacy manual, and the pharmacy manual spells out the collection of copays.

Q And it makes sense to me that at a point of sale, right, at a community pharmacy that the patient is charged a copay at the point at which they receive their medication. Correct?

A Correct.
Q I would assume that the pharmacy tech wouldn't hand the medication to the patient unless the patient pays the copay. Correct?
A For the most part, yeah, that's the idea.
Q So, how does that work with mail order. Clearly, the pharmacy and the patient are in different places, how does the mail order pharmacy collect copay?
A Mail order, you know, mostly they're going to process by credit card. They could have some type of accounts receivable, you know, if the patients, you know, regularly pay their bill every month, it would go on to AR, and then the patient would pay off their bill. If they're in arrears, I don't know that they are going to dispense the next medication.
Q Is it any other party's responsibility to collect a copay other than the pharmacy?
A No. There is --
Q Just the pharmacy?
A Nobody else would be able to, it's at the pharmacy.
Q Okay.
THE COURT: Just as at the physician's office for a doctor's visit?
THE WITNESS: Correct.
THE COURT: The provider.

BY MR. THOMAS:

Q Mr. Newkirk, have you ever seen an instance where a mail order pharmacy uses an EOB, an explanation of benefits, form in order to collect copays? Is that common or not common?

A Do you mean -- how do you mean? An EOB sent to a patient?

Q Correct. In order to be able to collect copay after the fact.

A Well, the only one who could -- if you're talking about a mail order claim, then, yeah, they could send out statements to the patient in order to, hey, you owe this copay, yes.

THE COURT: But that would be more unusual because typically they ask for payment up front and a lot of times, you know, for mail order that is, all, you know, they are asking for is three bucks for copay?

THE WITNESS: Yeah. They want to be paid.

THE COURT: Yeah.

BY MR. THOMAS:

Q Mr. Newkirk, have you encountered the term clinical guidelines?

A Yes.

Q What are clinical guidelines?

A Clinical guidelines is, you know, just at a high

level are, you know, the requirements when processing a claim if it falls within clinical guidelines, it will process through and without a reject. If you're outside of clinical guidelines, you know, could be dosing, could be a quantity, could have an interaction with another drug, then, you know, it falls outside of clinical guidelines and there could be an edit where it's going to fire a reject, then you got, then you need to deal with it at the pharmacy level.

Q And that's a front end edit. Correct? We talked extensively about the back end controls, this is at the front end. Correct?

A Correct.

Q My understanding, and correct me if I'm wrong, I'm sure it's rudimentary is that that's designed to prevent against common errors like a pediatric drug for somebody who's in a nursing home, something that doesn't even make sense?

A Male, female. It's a point of sale edit that PBMs create to help the pharmacist with their, you know, clinical guidelines, you know, here's a reject.

Q Who sets those clinical guidelines?

A The insurance company.

Q And the pharmacy is required to comply with it. Correct?

A Yes. They have the ability once they have a reject, to, you know, perhaps override it on their own with their

professional judgment or they might have to go through a prior authorization process. They may need to check with the physician, you know. There is -- there's a process of, you know, it's not getting around it, but dealing with a clinical rejection in a professional manner.

Q And if the pharmacy doesn't do that, what happens, the claim doesn't pay?

A The claim doesn't pay. You don't dispense the drug. The only way -- if you get a clinical reject and you decide, you know, it's an unpaid claim, you could theoretically charge cash for it, you know. It's not covered by your insurance, so you just convert it over to, you know, the usual and customary price or what you billed the insurance and the patient could theoretically -- you would have to, you know, it's your initials on it. You still own it. And if it's not clinically appropriate, I hope you don't dispense it.

Q Because the insurance company won't pay for it?

A Correct.

Q And if a patient wants the drug, they've got to pay out of pocket?

A Correct.

Q Mr. Newkirk, have you heard the term prior authorization?

A Yes.

Q What's a prior authorization?

A A prior authorization, it's a reject when you bill a claim and there is a step process for the pharmacy to get the drug approved. So, like a standard example is, you know, you're prescribed an expensive drug and there are cheaper alternative generics that are older, the insurance company might have a prior auth saying, have you tried this, have you tried these three drugs first, or you're required to do these before you're eligible for this. So, that would be a prior authorization process.

Q Is the prior authorization process at the front end or the back end?

A It begins at the point of sale. When you bill that claim, it's going to immediately fire, you know, this is, this requires a prior auth.

Q And it's to control the dispensing of drugs. Correct? So that the payors pay for only the pharmaceuticals that the payors decide they want to pay for?

A Correct.

Q Mr. Newkirk, have you heard the term utilization controls?

A Yes.

Q What is that?

A Utilization -- it's very similar to all of the other edits. It's, you know, like one utilization could be for a refill too soon, you know. They're looking at how often do

you utilize this drug. So, if you're allowed a 30 day supply and it requires 75 percent utilization, you know, it could fire for a refill too soon if filled too early.

THE COURT: Mr. Thomas, I'm just -- not emergency, but I'm looking for a logical stopping point, you know. I don't know how much longer you have on your direct, I mean, if you can finish up, you know, within the next half hour or so, that's fine, but if you want to take a break, I mean --

MR. THOMAS: Your Honor, now seems like a logical time for a break.

THE COURT: Okay. Yeah. Let's take about a 15-minute break. We've been going for an hour-and-a-half. We'll be in recess until quarter til 11.

MR. THOMAS: Thank you, Your Honor.

(Short recess.)

THE COURT: All right. Everyone have a seat. Proceed with your direct examination, Mr. Thomas. Mr. Newkirk, you're still under oath.

MR. HOBBS: Your Honor, before Mr. Thomas does that, I'm not sure what our time will be, but Mr. Montgomery has asked at noon he will step out of the courtroom, he has to take a call, and I just wanted --

THE COURT: That's fine, Mr. Montgomery. Let me just say on the record, now, you as a defendant, you have an absolute constitutional right to be here for each and every

part of these proceedings. Are you giving your consent that the proceedings can continue until you're finished with your phone call or would you prefer us to wait until your phone call is over?

DEFENDANT MONTGOMERY: Ideally if we could take a bathroom break for 15 minutes.

THE COURT: Okay. Yeah. Is it only going to be -- sure. We'll take, we'll just take a recess at noon. Okay. Let me know. Okay.

MR. HOBBS: Thank you, Your Honor.

THE COURT: We're starting -- we got about five minutes until 11. We got about an hour here, Mr. Thomas. Okay. Go ahead and proceed.

MR. THOMAS: Thank you, Your Honor.

BY MR. THOMAS:

Q Mr. Newkirk, have you heard the term dispensing limit?

A Yes.

Q What's a dispensing limit?

A To me a dispensing limit would be a quantity limit. So, there is a specific edit that would stop a claim from processing over a certain limit.

Q So, without a dispensing limit, I take it, as a lay person, that would mean that any amount could be dispensed?

A Without a dispensing limit, it would be considered

what I would consider more of a wide open benefit.

Q Have you heard the term maximum allowable cost?

A Yes.

Q In what relationship to compounding?

A In relationship, you know, MAC pricing really doesn't have a relationship with compounding drugs. It's more for generic pricing by the insurance companies.

Q And are there ever pricing caps in any PBM program in terms of limits on the amount that a PBM will pay just like a hard stop at a ceiling?

A Yes. Yes. You know, traditional retail claims or compound claims there can be a hard cap and there is many instances of that.

Q And concurrent with that, is there ever a process to waive the cap underneath certain circumstances?

A Yeah. Well, like, you know, Prime Therapeutics, you know, to me they're known for having hard caps on compounded claims. So, Prime does Blue Cross-Blue Shield of Texas. They had at this time a $500 cap. And if you billed a $600 claim, you had to go through a prior authorization in order to get a $600 compound covered. The problem was that it would be, it would never be approved.

Q Mr. Newkirk, we've had testimony in this case about a Tricare $1,000 cap on compound medications. Have you ever heard of a $1,000 cap on Tricare compounds?

A Yes. There was -- it was called -- the actual reject code they got was a cost exceeds max edit. It wasn't a hard cap, obviously, because pharmacies were able to call and get the claim overridden. It's, to me, it was very bizarre how this was happening, you know. Cost exceeds max to me is a hard edit. What the pharmacies found out is that, you know, if you bill a compounded claim to Tricare at $999, it would shoot right through. If you billed it at $1,000 or over, it's going to reject, cost exceeds max. And then the pharmacies in the beginning, you know, they would just lower the price to $999. Somebody figured out all they had to do, if I bill a $2,000 compound to Tricare, I make a phone call to Express Scripts for the cost exceeds the max. They're going to ask you what's in it. They would read off the ingredients, which to me is nonsensical because they already have what the ingredients are, they would generate the, what would you call it, the authorization to fill it, the override. And then the override would be in my understanding is for that particular claim for the next year.

Q So, am I correct in understanding that without the cost exceeds max override in the Tricare program that all compounds would have been reimbursed underneath the Tricare program at $999 or less. Correct?

A Correct. If Express Scripts would have had that as a hard cap, there would have been no claims over $1,000.

Q Who handled the administration or management of that waiver program, was it the PBM, ESI?
A ESI and Tricare together.
Q Together they did it?
A Yes is my understanding. I think I'm pretty sure that Express Scripts, they're the ones who field the phone calls, they're the ones who staffed it, and, you know, processed the overrides.
Q To your understanding, was it difficult or not difficult to get an override over the cost exceeds max?
A The only difficulty was you were limited to three claims at a time. So, if you had three rejects for, you know, cost exceeds max, you could call them up and they would do three claims at a time. And then you'd hang up and you'd call back and do it again.
Q Was it common? Were there a lot of waivers in the Tricare program on cost exceeds max?
A All day long every day.
Q Which generated --
A Around the country.
Q Which generated claims for compounds of $1,000 or more?
A Correct. And once you're over that $1,000 cap, there is no other cost edit at all, so it could be any amount theoretically.

Q Mr. Newkirk, I want to ask a little bit about marketing and marketing compliance in compounding. You're familiar with the CVS manual, are you not?
A Yes. Correct.
MR. THOMAS: I'm going to offer for the Court. This is Exhibit 113.
THE COURT: Has it already been admitted?
MR. THOMAS: Yes.
THE COURT: Okay.
BY MR. THOMAS:
Q Mr. Newkirk, can I direct you to the screen and take a look at the professional judgment and conduct.
A Sure.
Q See that? You read the testimony of the materiality witness, Steven McCall, from CVS Caremark in this case, have you not?
A Yes, I have.
Q And do you recall reading in Mr. McCall's testimony that he believed as a CVS Caremark representative or official that the professional judgment and conduct language in the manual applied to marketing. Do you remember Mr. McCall's testimony as to that matter?
A I do recall it, yes.
Q And you've read the professional judgment and conduct language there. Correct?

A I have.
Q Okay. As an expert in compounding compliance, Mr. Newkirk, do you believe that the professional judgment and conduct language that you see before you applies to marketing provisions?
A I don't see how you could make that stretch.
Q Is it compliant for pharmacies to market their compounding services?
A It apparently was because, you know, pretty much everybody, all of the compounding pharmacies in the country were using -- if you were billing any amount, you were, you know, in essence, you were utilizing, you know, marketers. And the insurance companies including CVS could readily tell.
Q And there are, are there not, independent third party marketing entities, correct, like not W-2 employees of pharmacies but 1099 independent contractors who just do marketing. Correct?
A Correct.
Q Is it compliant for pharmacies to utilize third party 1099 independent contractors to market their compounding services?
A You know, the compliance, the legal side, I'm not an attorney. I do know that, you know, this is how they were reimbursed across the country across the board at that time. That's how they were paid.

Q And, certainly, don't give us a legal opinion, you know you've been admitted as an expert in compound pharmacy compliance, and that's what we're asking. Do you know of, have you seen a claims discrepancy code that relates to marketing for compound services for pharmacies?
A I've never seen a discrepancy of, you know, the claim was a marketer.
Q With any PBM?
A With any.
Q To your knowledge and understanding, did any of the PBMs prohibit the use of third party marketers for pharmacies?
A Not that I'm aware of.
Q From your recollection, from your understanding, from your knowledge, have you seen an insurance plan behind the PBM reject any claims just based upon the use of third party marketing for compound claims?
A No. And it, you know, doesn't even make sense, you know. I turned on the news this morning and what do I see, commercials for prescription drugs, you know, marketing. You know, are those claims, those drugs going to be disallowed because they're marketing directly to the consumer? No. Makes no sense.
Q Have you seen any requirement in a contract or manual for a network pharmacy to notify a PBM or an insurance plan of the use of third party marketers?

A No. I can't even imagine a scenario where a pharmacy would call up and just randomly, you know, ask, or, hey, I'm using a marketer. That's just never happened.
Q Is marketing of a pharmaceutical a new phenomenon or have you seen it throughout your 30 years?
A Since pharmacy started.
Q Would it be indicative to a PBM that's receiving compounding claims from a pharmacy from a very wide geographical range, say across the country, as to whether or not that pharmacy is utilizing third party marketers?
A Yeah. I mean, absolutely. If I was auditing a pharmacy, and I walked in, prior to walking in the door, I'm going to preview the claims. And if I see that, you know, I've got a pharmacy in Chattanooga and a patient in New York and a physician in Iowa, and how did they get that prescription. I mean, you know, I can predetermine a marketer is involved. The PBMs had to have known just from the claims data itself.
THE COURT: You know, about this marketing phenomenon. Let me just say this. And I've made the observation, I'm probably the oldest person in the courtroom, which happens pretty often these days, but, you know, it seems like, and, of course, obviously, media, you know, has changed. That, you know, when I was younger, I didn't see as much prescription television ads, now, Bayer aspirin has been

obviously advertising on television, you know, throughout my lifetime. Okay. But it seems like that it's a more recent phenomenon where, you know, prescription medications were advertising at least on television to me.

Now, having said that, you know, I think that before I was an adult, you rarely saw lawyers advertising on television. And in the '70s, the U. S. Supreme Court changed the rules and now you can't avoid lawyers' advertisements on television. So, is there -- has there -- I mean, am I wrong that at least I didn't see it on television as frequently when I was younger as I do now. I mean, you can't turn on the television without seeing a prescription. They're always careful to say, consult with your physician and all of that, but.

THE WITNESS: Correct.

THE COURT: Am I wrong about that?

THE WITNESS: I think it's absolutely grown, you know, the direct-to-consumer marketing has grown especially by television.

THE COURT: But is there -- has it grown as a result of any specific legal change? Now, again, I can't remember the name of the case, but I do think in the context of the lawyer advertising that there were real questions whether it was ethical until the Supreme Court said, I believe it was in the '70s that, no, it's ethical. And lawyers obviously have

really taken the Supreme Court up on that.

THE WITNESS: I don't really know the trigger. I know that Pfizer reps are greatly curtailed in how they work directly with doctors, you know, you can't pay for expensive, you know, giant expensive meals, you can't fly them all over the country, you know. They've cut back on that. Has that resulted in larger direct-to-consumer marketing on television, you know, probably in some part, yeah.

THE COURT: Okay. Go ahead.

MR. THOMAS: Thank you, Your Honor.

BY MR. THOMAS:

Q In terms of the PBM's realization of the use of third party marketers by network pharmacies, was that after the fact or realtime or both?

A What do you mean?

Q Well, for instance, let me offer -- this is a government's exhibit in this case. This is a prescription. Correct? Looks to be -- well, instead of me telling you what it is. Mr. Newkirk, you know compound pads and compound prescriptions much better than I do. What does this appear to be?

A This is just a script pad for multiple different compounds. I've reviewed thousands of these.

Q And that's pursuant to audits. Correct?

A Correct. You have to --

Q You audit, you see the script?
A In order for a PBM -- when you bill a claim there is one important thing. An insurance company does not have an image of the claim, all they have is the data entered, the quantity, the drug, the price on it. What they do not have is an image, but once they audit the image, then they look at the prescription. And like what you can see here is, you know, clearly, a rep ID.
Q What's a rep ID?
A This identifies, you know, to me, this identifies as soon as I see this on audit, I know that there is marketer involved here.
Q A representative?
A A marketing representative. And, clearly, you know, I can pretty much determine from the location of the pharmacy and the patient and the doctor, but this clearly indicates a rep ID. And the PBMs saw that. They saw any time they audited a claim and they saw anything like a rep ID or ID or, you know, an unusual number, they knew 100 percent there was a marketing rep involved.
Q And would that generate a claim discrepancy?
A No, it would not.
THE COURT: Is there any requirement that a script have a rep ID on it, is there a legal requirement? Why do they --

THE WITNESS: No. No. Not at all.

THE COURT: Well, why does some people, why do people even bother to put it on?

THE WITNESS: That would be for the pharmacy to understand the rep that, you know, the marketing rep who's working with the physician, you know, who are they basically in agreement with, who does the script belong to in essence.

THE COURT: Why does a pharmacist care who it belongs to other than the physician? Now, I understand why they would care, but, I mean, why -- so what? Okay. A marketing rep talked, for instance, a physician into, you know, writing a script. I mean, that's on the physician, not the pharmacist. Right?

THE WITNESS: Right. Well, the pharmacy if you've hired marketing reps, you want to know who's responsible for which --

THE COURT: Okay. So, they can compensate them, I guess?

THE WITNESS: Correct.

THE COURT: Okay. I get it. Okay. Okay. Okay. I'm sorry. I wasn't following you. So, that's really an internal thing for the pharmacy to figure out, okay, well, who do we give credit for?

THE WITNESS: Exactly.

THE COURT: Okay. All right.

MR. THOMAS: Your Honor, this is a government's exhibit marked document, but I'd like to make it an exhibit and get it entered.

THE COURT: Okay. Any objection?

MR. CLARK: No, Your Honor.

THE COURT: Admitted.

MR. THOMAS: I have no idea what number it is.

THE COURT: You need to mark it so Ms. Capetz can -- yeah.

MR. THOMAS: Yes, sir.

(Defendant Wilkerson's Exhibit 5 was received into evidence.)

BY MR. THOMAS:

Q Mr. Newkirk, for the benefit of the Court, please describe how much control PBMs utilized over pharmacy marketers, network pharmacies, a lot, a little, often, not often, please describe.

A Zero authority. They don't have -- they're not contracted with the marketer. They're contracted with the pharmacy, and, you know, the plan sponsor. That's it. They're not even contracted with the doctor.

Q In your opinion as an expert in compound pharmacy, is it compliant for pharmaceutical marketers to market directly to physicians, the physicians who would be writing prescriptions?

A Yes. It happens every day.
Q Same question but as to potential patients. Is it compliant for a pharmacy to utilize third party marketers to market directly to the general public?
A From what I can tell, big pharma does it every day. Look at a commercial.
Q Can you offer the Court any specific examples?
A Yeah. Just, you know, commercials. Billboards. You know, direct-to-consumer marketing is, you know, prevalent.
Q How about advertisements that direct patients to physicians? We've got testimony in this case that we have talked about the generalized commercials where there has been direct-to-patient, direct public marketing saying, you know, please ask your physician, if you don't have a physician, we're happy to recommend one to you. They've got lists. Are you familiar with that, Mr. Newkirk?
A Yeah.
Q Is that compliant?
A I think so. You know, if I go to UPMC, University of Pittsburgh Medical Center, that's where we have our insurance through, and if I go online and I need a doctor, they're going to direct me to a UPMC doctor, 100 percent.
Q Would it be compliant for a pharmacy to direct patients to specific physicians in order for those physicians

to be writing prescriptions?
A I think so, yeah. I mean, that's part of their job. If you need a specialized medication, you're going to want to send them to a physician who's knowledgeable.
Q And, finally, would it be a compliance problem if that communication were directed by the pharmacy's third party independent 1099 marketers to the patients to say if you don't have a doctor, we can recommend one for you?
A Yeah. I don't see that as a problem, not that I know of.
THE COURT: Okay. Let me stop you there because, I mean, that's going to be a big issue in this case. And, I mean, that is a difference in what you see on television and what was allegedly going on here, in that the television ads say see your physician. Okay. You, patient, see your physician. Here, there is an allegation by the government that the marketers were steering -- I think there are two parts to the government's allegation. That the marketers were steering patients to particular physicians, a small group of particular physicians. That's the first part. The second part is that the government alleges that the marketers somehow exercised control over the physicians' exercise of their professional judgment to the extent it was compromised. Okay?
THE WITNESS: Okay.
THE COURT: Now, this is my job, not yours, but if

the government can prove both of those things, that the marketers steered individual patients that they approached initially to individual particular physicians, and, secondly, that those particular physicians' professional judgment was compromised at the behest of or that the marketers caused the physician's professional judgment to be abandoned. Okay?

THE WITNESS: Uh-huh.

THE COURT: Is there anything wrong with that? And, I guess, to say if there is anything wrong with it, is there anything, to your knowledge, illegal about it?

THE WITNESS: Illegal? A marketer can --

THE COURT: And who committed the illegality, is it the physician or the marketer or both?

THE WITNESS: The physician. A marketer could yell at a physician all day long --

THE COURT: Or pay them?

THE WITNESS: Or, well, as long as you're paying correctly, you know, according to, you know, how a physician should be paid.

THE COURT: Well, to the extent it's a bribe, I mean, but --

THE WITNESS: That could potentially be a problem. Let's assume you're paying correctly. A marketer could yell at a physician all day long, I want you to prescribe this. And the physician has a, you know, their medical license, you

know, their initials are on the line.

THE COURT: Yeah.

THE WITNESS: And if they do what the marketer says, they're out of their minds, like I'm a pharmacist and I got, I have a patient yelling at me to dispense a drug, and if in my professional judgment I don't want to do it --

THE COURT: What if they don't care what happens to their license, what happens to their license? I mean, in which it's still on them if they are willing to risk their license?

THE WITNESS: It still comes to, you know, who has the prescribing authority, you know, per state law. It's their license.

THE COURT: Yeah. Okay. All right. Go ahead.

MR. THOMAS: Thank you, Your Honor.

BY MR. THOMAS:

Q Following up on the Court's concerns and questions, Mr. Newkirk, have you experienced circumstances whereby there is at least an arguable conflict of interest say in a hospital where a prescriber, say it's a nurse practitioners is an employee of the hospital, and if the nurse practitioner prescribes a medication, assuming it's going to be dispensed by the hospital, right, an outpatient basis, how can you tell whether or not that the independent prescribing responsibility that you had just mentioned in response to your last question,

how can you tell that's been compromised?

A Exactly. I've audited in hospital-owned pharmacies in hospitals either in the basement or in the first floor, you know, retail setting, the hospital owns the pharmacy.

THE COURT: So, you're saying, basically, that at the end of the day, anybody in the system is entitled to rely on the integrity of the licensed professional? I mean, that's just the way the system is set up.

THE WITNESS: It's the basis.

THE COURT: Okay.

BY MR. THOMAS:

Q Is it common to have nurse practitioners as employees of hospitals?

A Absolutely. Any prescriber --

Q Is it common for nurse practitioners to prescribe medications?

A Absolutely.

Q Is it common for the hospitals to be dispensing those medications that the nurse practitioners who are employees wrote prescriptions for?

A If they have a pharmacy and just like if they're doing x-rays or anything else.

Q Is it common for a hospital to be essentially getting reimbursed more for the medications that they dispense than they paid?

A Yeah. Absolutely, you know, unless --
Q Am I correct in understanding it's not a per se discrepancy on a claim?
A It is not a discrepancy.
Q And there is not any specified discrepancy that you've seen in an audit, correct, where there would be a discrepant claim based upon the same entity employing the prescriber and doing the dispensing. Correct?
A Correct. There is no discrepancy like that.
Q Let me take you back to CVS representative Steve McCall's testimony. Do you recall where he was discussing prescribers, nurse practitioners in CVS Minute Clinics. Do you recall that testimony?
A Yes.
Q From my reading of that testimony, and please tell me if you don't agree, Mr. McCall even stated that that's not a conflict of interest that no matter what, the nurse practitioners who are working in Minute Clinics have an independent responsibility to prescribe in the patient's best interest period, not in CVS's best interest but in the patient's best interest?
A Correct.
Q Is that correct?
A Correct.
Q In this specific circumstance, Mr. Newkirk, and

you're aware of the facts in this case, there are allegations from the government that it is a per se illegal event to have one entity controlling the prescribers as an employee, correct, and that entity or another affiliated entity making a profit off of medications that those nurse practitioners are prescribing. You're aware that those facts are in this case?

A Correct. Yes.

Q What is your professional opinion as an expert in compound compliance, is that a non-compliant event to have an entity both or dual entities that are both controlled by the same person, or persons, to both employ the prescriber and make money off of the prescriptions, is it non-compliant?

A It is not non-compliant. There is multiple models that do this every day.

Q And how do you find non-compliance, is it a blanket event over all of the claims or do you do it on a claim by claim basis?

A It has to be on a claim by claim basis and that's, you know, how PBMs audit, you know. It is specific claims in order to determine a specific discrepancy.

Q We've had testimony in this case, Mr. Newkirk, we discussed it briefly, that the government is alleging that there is a requirement for marketers to communicate to a PBM or to an insurance plan what they're doing. You're aware that that's testimony that's been presented in this case?

A I saw that, yes, I did see that testimony.
Q In your background and in your experience over the last 30 years as an auditor in the pharmacy space, as an expert in compound pharmacy compliance, have you ever seen a requirement in any contract or manual that a marketer is required to reach out to a PBM or an insurance plan to let them know what they're doing?
MR. CLARK: I want to interpose an objection at this point. I think that mischaracterizes, one, the testimony, and, number two --
THE COURT: I need to be familiarized -- tell me what witness, I mean, I'm not saying they didn't, remind me which witness, which government witness earlier said that a marketer is under some sort of either legal or ethical obligation to disclose their existence to, who, a PBM or an insurance company?
MR. THOMAS: Primarily, Mr. McCall stated that it would be material to a determination --
THE COURT: Would be material. Okay. But, I mean, now, that may be different from either a legal or an ethical obligation. Right? Let's be -- I think there is a need to be precise here what we're talking about. I do believe that Mr. McCall may have testified to that. Do you disagree with that, Mr. Clark?
MR. CLARK: Mr. McCall testified that was a fact

they would have liked to have known along with others. I don't think he ever said that a marketer is required to --

THE COURT: I mean, that's something that I'm probably going to let you both sides cite, you know, the transcript to me in their brief, precisely what he said, but I do believe that -- yes. I will just state, if you can dissuade me, or, you know --

MR. THOMAS: Your Honor, I'm happy to restate.

THE COURT: I believe there is a difference between materiality and a positive legal requirement of disclosure. Yeah.

MR. THOMAS: I'm happy to restate, Your Honor. And I will bring up Mr. McCall's testimony at a later point in direct.

THE COURT: Okay.

BY MR. THOMAS:

Q But I would offer that from my reading of Agent Kriplean's testimony, he stated that the marketer could pick up the phone, could pick up the phone and disclose to an insurance plan that they are being paid for marketing the compound?

THE COURT: But, I mean, what's remarkable about that? I mean, if that was his testimony, I could pick up the phone and call the IRS and tell them, hey, I'm committing tax fraud every day, I usually choose not to do that, okay, unless

I think they're on to me already.

MR. THOMAS: May I restate the question, Your Honor?

THE COURT: Yeah. Go ahead.

MR. THOMAS: Or would you prefer I move on?

THE COURT: Yeah. Go ahead.

MR. THOMAS: Thank you, Your Honor.

BY MR. THOMAS:

Q Mr. Newkirk, I had offered that we've got testimony in this case from the case agent that one of the solutions that a marketer could utilize in order to remove the discrepancy, in order to remove the problem, is to just report to the PBM or report to the insurance company what they're doing. Hey, I'm marketing drugs on behalf of a pharmacy. Have you seen that in your experience?

A Never.

Q In your experience are there any limitations as to the types of patients that, the types of insurance that the patients have in terms of direct-to-patient marketing like is it legal for Prime Therapeutics or legal for ESI or is it across the board?

A Across the board. It's not addressed.

Q Does that include Tricare patients?

A That's a more difficult question. I think that that would be -- you'd have to look at the statutory language and I'm not comfortable answering that question 100 percent.

Q Well, let me ask the question this way. ESI is the PBM for Tricare. Correct?
A Correct.
Q Are you aware of a limitation in the ESI provider manual in terms of marketing to Tricare patients?
A I'm not aware of any limitation.
Q Are you aware of any limitations in the ESI manual regarding how it is that marketers can be paid? Do they have to be W-2s, do they have to be 1099s, do they have to be paid on productivity. Are you aware of anything?
A During this time period, absolutely not.
Q When you say during this time period, 2013 to 2015?
A Correct.
Q So, the PBM manual was silent as to whether or not marketers marketing to Tricare patients could be paid based upon productivity?
A I don't know that you can even find the word marketing in the manual.
Q Following up on our earlier question I had asked, there is nothing in the ESI manual that pertains to Tricare patients that addresses whether or not a marketer has got to be a W-2 or a 1099. Correct?
A Correct.
Q Mr. Newkirk, was there any confusion in the industry as to how to classify Tricare in 2013, 2014, 2015? Was there

any confusion in the industry as to whether or not it was public or private?

A I mean, it was run through Express Scripts. So, was there confusion or not, it was just a, you know, a plan administered by Express Scripts, so.

THE COURT: The pharmacy plan was administered by --

THE WITNESS: Correct.

THE COURT: -- Express Scripts? I mean, Tricare -- let's -- okay. Tricare itself was in fact a government plan, at least I've heard testimony that, hey, you know, Congress had to appropriate additional funds, so, I mean, that's the definition of a public insurance plan. Now, having said that, just like every aspect of the federal government, certainly, including the Department of Defense, they contract out this work to private companies to do that for them. Okay.

THE WITNESS: Correct.

THE COURT: Best example I know is, yes, the Lockheed Martin and other like-minded companies create the weapons systems that our government uses to fight its wars. Okay. So, I mean, you know, there is nothing unusual about a, about the government contracting with a private company to administer aspects of its plan whether it be pharmacy benefit management or weapon production. Right?

THE WITNESS: Right. Correct.

BY MR. THOMAS:

Q Mr. Newkirk, are you aware of any differences between Tricare and Medicare, are they the same program, are they different?

A They're different.

Q And I've got in my notes from your testimony earlier today that while Tricare uses ESI as a PBM that the Medicare program utilizes a different front end for their pharmaceutical claiming system. Correct?

A Well, Medicare contracts with nearly every PBM out there in order to administer the Medicare benefit.

Q So, the Medicare program uses PBMs like the Tricare program?

A Correct, including Express Scripts.

Q Do you believe it's a compliance concern if a marketer utilizes submarketers or sub-submarketers?

A I don't see how that's a compliance issue from a PBM or an audit perspective.

Q Have you ever seen a claims discrepancy having to do with the use of submarketers or sub-submarketers?

A No, not at all.

Q Is there any -- is there any code for the denial of a claim based upon having another person pay the patient's copay other than the patient?

A No. When you're looking at an audit and proof of

collection of copay, the PBM is basically just verifying that the copay was collected.

Q Do the PBM manuals specify that only the patient can pay the patient's copay?

A Not explicitly. I mean, there is language, you know, that leads that way, but there is no restriction that, you know, if I go in and my son has an antibiotic, can I pay his copay? Absolutely.

THE COURT: Let's say, but, if there is language that could be accurately interpreted to, you know, in a PBM manual to prohibit a third party from paying a patient's copay, well, if someone were to run afoul, if a pharmacy were to run afoul of that provision, the proper legal remedy, I believe, would be breach of contract. Right?

THE WITNESS: For the particular individual claim, yes, upon audit.

THE COURT: Yeah. I mean, it's a breach of contract?

THE WITNESS: Right. But then, also, you know, manufacturer coupons are used every single day to reduce copays.

THE COURT: Yeah. Well, yeah. Okay.

BY MR. THOMAS:

Q Manufacturers reduce copays. Correct?

A Every day all day long.

Q Organizations reduce copays?
A There are many pharmacies out there that work with the local church and say somebody can't afford their medications, you know, the church will step up and pay those.
Q Patient assistance programs can be approved by the Medicare program. Correct?
THE COURT: Well, I mean, how many times have I heard if you can't afford your medication AstraZeneca may be able to help, you know.
THE WITNESS: They're designed that way in order to, you know, sustain the business model.
THE COURT: Okay. Well, it creates public good will. Hey, this is not just, this is maybe primarily but not just a greedy pharmaceutical company, you know.
THE WITNESS: We're willing to pay for a couple of these people who can't afford it in order to allow the processing of these drugs, and, you know, you know, if you don't have the means, we'll help, and if not, we have the manufacturer's coupon to take your $1,000 copay down to 20 bucks.
THE COURT: Yeah. Right.
BY MR. THOMAS:
Q Mr. Newkirk, have you ever seen a claims discrepancy where a marketer paid for a patient's copay?
A I have not.

Q In 30 years?
A No. I've never seen that discrepancy written up.
Q Is there a discrepancy that's dedicated to paying someone else's copay?
A They would have to create the discrepancy because in the current manuals and the manuals at that time there is no discrepancy identified as someone else paid the copay.
Q Mr. Newkirk, is there any requirement that you've seen that you're aware of either in contract or in a PBM manual that requires the disclosure to a patient of the cost of the medication to the insurance plan?
A No. No. I mean, by who, by anybody?
Q That was my next question. Is the patient's physician required to disclose to the patient the cost to the patient's insurance plan for the medication that the doctor is writing?
A They're not only, you know, not required, but they don't know the cost of the medication.
Q Is the pharmacy required to disclose to the patient the cost to the patient's insurance plan the cost of the medication that the pharmacy is compounding and dispensing to the patient?
A They're not required, and in some instances, they may even be prohibited.
THE COURT: Actively prohibited? Yeah.

THE WITNESS: Actively prohibited.
BY MR. THOMAS:
Q Because pricing is proprietary. Correct?
A Pricing is proprietary, but they're just not required to, you know, when the patient picks up the medication, the cost in effect for the patient is a copay. You have a $10 copay, how much did that cost, it cost $10.
Q And, finally, my last question in this line of questioning. Is it required for a marketer who's working for a pharmacy, who's in that work, the insurance plan and the PBM to disclose pursuant to direct-to-consumer marketing the cost to the patient's insurance plan or PBM of the medication at issue?
A Absolutely not. And it's, to me, it's probably impossible to do that.
Q In your career have you ever seen a claims discrepancy due to failure to disclose to the patient the cost to the patient's insurance plan of the medication at issue?
A No, it doesn't exist.
Q As it relates to compounding, even if there were requirement for the marketer to disclose to the patient to whom the marketer is marketing the cost of the compound, how is it that the marketer would know the cost of the compound?
A They really couldn't, you know, perhaps, because a compound has say seven different ingredients depending upon

where they're sourcing the chemicals or the drugs, and put it together, it could have all different types of pricing, the final price and then, you know, what the insurance company actually reimbursed. There is just no way. The only entity that's going to know the final cost of the compound is the pharmacy.

Q Are you aware in any other sector of health care where there is a requirement to disclose to the patient the ultimate cost to the patient's insurance of goods or services that the patient is about to receive?

A I'm not aware.

Q Not in hospitals. Correct?

A In the pharmaceutical side, no.

Q Again, Mr. Newkirk, you reviewed the testimony of Steve McCall, the CVS representative, that testified in this case. Correct?

A Yes, I did.

Q Do you recall Steve McCall testified that CVS Pharmacy doesn't tell a patient what Caremark paid for the prescription?

A I recall that, yes.

Q And are you aware in any instance of a pharmacy being required to provide lower cost alternatives based upon a prescription?

A Only in, you know, brand generic substitutions.

But, you know, as far as compounding drugs, it's up to the pharmacy to choose who they're sourcing the drugs from for the particular compound.

Q And in the industry, are you aware, are there any rules or regulations that require, I mean, apart from the manual, apart from the contracts, are there any regulatory or statutory requirements for disclosures of manufacturers in direct-to-patient marketing to disclose cost of medications to the patient's insurance plan?

A No, not at all. For a manufacturer to tell the price of their drugs? I've never seen it.

Q In fact, are you aware of a relatively recent case in which Health and Human Services promulgated a rule, a proposed rule that would force manufacturers in their direct-to-consumer marketing like on television, to disclose the cost of the medication so that the patients would know when I go to my doctor to ask for a medication, I know what my insurance plan is going to pay? Are you aware of any current opinions that were just issued by federal courts relating to that?

A Yeah. HHS wanted to implement that rule to have pharmaceutical advertising, you know, list the price. And big Pharma, Merck, of course, challenged them on it. And my understanding from a layman is that, you know, they sided on the side of the pharmaceutical companies and struck it down.

Q That's the *Merck versus HHS* case that came out just several months ago. Correct?
A Correct.
Q That proposed rule was struck?
A Yes.
Q So even the manufacturers aren't required to disclose pricing to patients in direct-to-patient marketing?
A Correct. And your commercials that you see, you're not going to see a price at the bottom of the line scrolling across.
Q Mr. Newkirk, back to compound medications. Would it be a compliance concern if medications dispensed to a patient, compounded medications were somehow ineffective, they just didn't work. Is that a compliance issue?
A You know, if they don't work, I mean, it's up to the physicians, you know, prescribing them, you know, medical necessity and the appropriate drug, whether or not it works is something that you pretty much figure out down the road and you might have to try something else.
Q Would it be a compliance concern if the prescription that was generated was not generated pursuant to a physician patient encounter? Would that be a compliance issue?
A It would be for the physician if there is not a valid physician patient relationship, yeah, that's a definite problem for the physician. You know, how does a pharmacy tell

whether there is a valid patient, you know, physician relationship. I mean, when you get a prescription that comes in, you're filling 1,000 prescriptions a day, you know, that's on the physician to have that valid relationship for, you know, for the most part from the pharmacy perspective.

Q Is there a discrepancy code applicable to the pharmacy in the event that somehow the encounter between the doctor and the patient was non-compliant?

A I've never seen one.

Q It's not a pharmacy problem, is it?

A It is not a pharmacy problem.

Q Because it's the responsibility of the physician?

A Correct.

Q Okay.

THE COURT: When you say a valid patient doctor relationship, how would you define a valid patient doctor relationship?

THE WITNESS: It's going to come down to the individual state laws and rules and regulations. So, you know, states may require that you have a physical encounter. Telemedicine is being mandated, you know, the allowance of it by the federal government, because, you know, access to meds. So, can you have a valid relationship over the telephone now? Yes. Does it have to be a video? Maybe, perhaps, depends upon the state law, but, you know, it's determined by the

state.

THE COURT: Okay.

BY MR. THOMAS:

Q Mr. Newkirk, would it be a compliance concern if a pharmaceutical marketer, third party marketer, were paid through an individual LLC as opposed to getting paid personally?

A I'm not an expert on, you know, how a, how corporations are set up and how they're paid.

Q Fair enough. Let me reask that question. Not a great question. Have you seen a discrepancy code --

A No.

Q -- related to paying a marketers' LLC versus paying a marketer directly?

A No. No, that has never come about.

Q Would it be a compliance concern to you if a patient and a marketer were one in the same person, that essentially a sales rep were getting paid a commission based upon their own personal compounded medication? Would that be a compliance concern?

A I don't know. It would be a claim you could audit. Would it be a compliance concern? I don't know. There is not a discrepancy code for it.

Q That was going to be my next question. No discrepancy code?

A Right. There is no discrepancy code, you know.

THE COURT: Well, let's explore that a little bit further. Okay. So, you say that would be perhaps a flag on an audit if you became aware that a patient themselves had been paid a commission somehow for, you know, the prescribing of that medication for the individual. Right? Because it provides a financial incentive for that individual to receive that prescription as opposed to a medical incentive. Right?

THE WITNESS: Right.

THE COURT: But as long as there is a physician signature on the script.

THE WITNESS: (Witness moves head up and down.)

THE COURT: Okay. Yeah. What are you supposed to say, well, you are going to almost 100 percent of the time rely on that physician's signature or prescriber signature?

THE WITNESS: That's their, that's their medical license on the line.

THE COURT: All right. Go ahead.

BY MR. THOMAS:

Q Given medical necessity for the compound medication, do you think that that would be discrepant?

A As long as -- no, it's not a discrepancy.

THE COURT: What I hear him saying is as long as you got that licensed professional signature on the script, that may look fishy, but, you know, seems to be acceptable.

BY MR. THOMAS:

Q Because a sales rep may have pain that could be treated by a topical medication?

A A Pfizer rep could be treated with a Pfizer drug and have a zero-dollar copay.

THE COURT: I bet you there are Pfizer reps that take Lipitor.

THE WITNESS: I bet there are. My wife worked for GlaxoSmithKline for 17 years until they closed GSK in Pittsburgh. And we used to get brand name Glaxo drugs for zero, did that affect us.

BY MR. THOMAS:

Q Did your insurance company, and I don't mean to get personal, but you brought it up, did your insurance company ever --

A They could have audited --

Q -- give any kind of complaint --

A Absolutely not.

Q -- and say you're getting, you're double dipping?

A No. Absolutely not.

Q Mr. Newkirk, I'd like to go into the final series of questions that I'd like to ask, to ask of you. Again, you read Steve McCall's testimony, the CVS Caremark representative?

A Correct.

Q I'd like to address some of the matters that he addressed as a materiality witness for the government. The government asked of Mr. McCall, and, of course, you read his testimony, whether it would be material as to a decision for CVS Caremark to pay a claim or not pay a claim if customers were not paying a copay. Would that be in and of itself a discrepant claim based upon your experience?

A On the individual claim itself. You have to audit the claim in particular in order to determine that. You know, a generalization, in the end, you have to audit the claim.

Q Yes. And was there a requirement for the pharmacy to collect a copay, if no matter what the pharmacy did they couldn't collect a copay, would that generate a clawback for the payment to the pharmacy?

A Yes. Proof of collection of copayments were -- they became standard auditing techniques.

Q So, it's a requirement not to just try, it's a requirement that literally get the copay and if for some reason, like you say, I don't know, the patient is indigent and they can't pay, that's going to generate a clawback?

A It will absolutely generate a clawback. You could have a $20 copay and collect $19 of it and upon audit if you still haven't collected that last dollar, it's 100 percent recoupment of that claim.

Q And that's determined on a claim by claim basis?

A 100 percent, yes.
Q Is there any other way to determine that other than a claim by claim basis?
A No. I mean, you can't extrapolate, you know, if you find three out of 10 claims, that's 30 percent and extrapolate against the board, across the board, you're not allowed to do that audit wise for PBMs. It's been shot down in court, at least that's what I was, you know, trained at Medco. We could not extrapolate anything. Everything was on a claim by claim basis.
Q What if a marketer paid the patient copay, would that generate a discrepant claim?
A It would, it would not generate a discrepancy. When the copay is audited, what the PBM requires is payment and proof of payment. So, who paid it, really, at that point does not create a discrepancy.
Q Do you recall that Mr. McCall stated that CVS Caremark would find it material if CVS Caremark knew that the same entity or the same person was both earning commissions from a pharmacy for the promotion, sale of compounded medications, and as well as employing prescribers who are writing those prescriptions. Do you recall that testimony?
A I do.
Q Would you find that on a claim by claim basis to be a discrepancy, would you deny that claim?

A There is not a discrepancy type for that, you know, that scenario. I don't know how, you know, if you're in a pharmacy auditing a claim, you're looking at reviewing the claim, you're not going to know the ownership structure of a physician's office. I don't see how that could ever be a discrepancy. And even if they knew the ownership structure, there is not a discrepancy type for that.

Q And from my notes, I jotted down that you had stated that given independent clinical judgment, which is the responsibility of the prescriber, that's the test. Correct?

A Say that again.

Q Surely. From my notes, I have that you had said to me in response to one of my questions that no matter what, discrepancies are going to be found in the event there is a lack of medical necessity, for whatever reason, but that is the sole determination of the patient, I'm sorry, the sole determination of the prescriber and not anyone who employs the prescriber. Is that correct?

A Correct.

Q Mr. Newkirk, and this is a little bit repetitive because we had just talked about this with marketers getting paid on their own prescriptions. Mr. McCall, you'll recall from his testimony, stated that he would find it material as a CVS Caremark official as to whether or not that a person who's both a patient and a sales rep. So, I'm going to ask you. He

found it material. Would you find it discrepant?
A You would have to audit the individual claims in order to identify a discrepancy.
Q Do you recall from Mr. McCall's testimony that he believed that it would be material to the CVS Caremark determination as to whether or not to pay a claim as to whether or not a patient contacted a nurse practitioner or the nurse practitioner contacted the patient. Do you recall that testimony?
A Not quite as clear as I do, but I understand what you're asking.
Q All right. Let me rephrase the question. Would you find it to be discrepant in the event that a nurse practitioner contacted the patient as opposed to a patient contacting a nurse practitioner to get the encounter to write the prescription for the patient? Would you find that discrepant?
A I would not, no. There is no discrepancy for how a physician and a patient interact.
Q Have you ever seen a claims discrepancy based upon that?
A No, I have not.
Q Do you recall any testimony from Mr. McCall regarding any input of the marketers into what compounds went into the ultimate prescription? Do you recall that testimony?

A What ingredients?
Q What ingredients.
A Yes.
Q Would you find it to be discrepant in the event that a marketer had any control over what went into an ultimate compound?
A Well, no, it still comes down to the prescriber, you know, in the end the prescriber has to prescribe the medication. And, you know, it's their signature, their authority, and that's who it rests with.
Q Have you ever seen a claims discrepancy based upon that, a marketer having any effect upon what went into a compound?
A No, I have not.
Q Mr. McCall testified that he believed that it would be material to a CVS Caremark decision as to whether or not to pay a claim in the event that CVS knew that marketers were essentially directing prescriptions to particular compound pharmacies, right, picking one compound pharmacy over another compound pharmacy. Would you find that to be a claims discrepancy?
A No. Because, again, it's going to come down to the physician prescribing the medication. And it's going to come from the physician's office. And in the end, the physician and the patient are working together, you know, hopefully to

determine where they can send this medication.
Q Have you ever seen a claims denial based upon a marketer directing a compound prescription to any given pharmacy?
A No, I have not.
Q Okay. And we've covered this, but I'm going to ask you again. Have you ever seen a claims discrepancy based upon the use of a compound pharmacy pad because Mr. McCall stated that he believed it would be material to a CVS Caremark determination? Discrepancy or no?
A No, there is no discrepancy. And I don't understand that testimony because, you know, all of the PBMs were well aware of compounding pads, preprinted prescription pads because they audited thousands and thousands of them and never wrote them up as a discrepancy for being a prescription pad.
Q It's my understanding that Mr. McCall had testified that it would certainly be a material matter for CVS Caremark to pay a claim if it appeared that multiple members of a single family were receiving what appeared to be relatively similar or the same compounds? Would you find that event to be discrepant? Would you have a claims denial concern?
A Well, the claim would have to be audited, you know, for the family members and then it's still going to rest on the prescriber prescribing the drug. If the doctor is writing for it, they're determining the medical necessity of the

medication.
Q Do you ever recall seeing a claims discrepancy based upon the same family getting similar prescriptions?
A No. And in the compounding world, this was, this was quite common. And I think I would argue traditional retail pharmacy, this is, you know, common as we become older and all, you know, family members have diabetes, are they going to be treated with common diabetes medications? Absolutely.
Q From my notes, I have that the government inquired of Mr. McCall whether or not there would be any concern whether or not that marketers approached patients versus patients approaching marketers. Would you find that to be a claims discrepancy in the event that that were true?
A There is no discrepancy type for, you know, the marketing entities at all.
Q No claims discrepancy noted?
A Correct.
Q Do you ever recall seeing a claims denial based upon that?
A No. I have never seen a claims denial on that.
Q The government also asked Mr. McCall on direct testimony whether or not that customers, patients that had been offered money, the same patients who received medications, that CVS Caremark would consider that to be a

material event as to whether or not that they would pay the claim. Would you find that to be a discrepant claim?

A You would have to -- that would be a claim you'd want to audit and determine is there, you know, something invalid about the claim. Is there a discrepancy type for that? It doesn't exist. You would have to, you know, create it.

THE COURT: But I heard his testimony, I think, previously that that would raise something of a red flag at least to look into it further.

THE WITNESS: Yes. Of course, you're going to have concern, but you're still, you have to audit each and every claim.

THE COURT: Yeah. That's what I understood your testimony to be. All right.

BY MR. THOMAS:

Q Is there a discrepancy code for conflict of interest or paying patients, giving them an incentive?

A No.

Q Mr. Newkirk, are you aware of any -- and you're an auditor -- of any audits that were applicable in this case? Were you aware that there was a Blue Cross audit at some point?

A Yeah. Yes.

Q It's a very difficult number to read, but this is a

government's exhibit in this case. Mr. Newkirk, have you seen this documentation previously?

A This particular one, I don't know if I saw this page, but I just read it.

Q I'll give you just a moment to look at that.

A I did review this.

Q Is this an audit result?

A This is, it looks like an audit result from, I think this was Blue Cross Blue Shield. And they had some concerns about family members. And they did a chart review and reviewed it, and, you know, gave it their stamp of approval.

Q Chart review of Karma Medical Spa patients. Correct?

A Correct.

Q And there were no aberrant claims findings. Correct?

A Correct.

Q Any claims denials that you're aware of pursuant to this audit?

A Not that I'm aware of.

Q Any other audits that you're aware of that applied to Karma Medical Spa or Top Tier Medical?

A Not that I'm aware of.

THE COURT: Mr. Thomas, we've got about five more minutes before I'm going to take a break.

MR. THOMAS: I'm wrapping up, Your Honor.

THE COURT: Okay.

(Brief pause.)

MR. THOMAS: Your Honor, could we take a very brief recess?

THE COURT: I tell you what, why don't we go ahead and take a recess until 12:15. You think that will give you time to complete your phone call, Mr. Montgomery?

DEFENDANT MONTGOMERY: Yes, Your Honor.

THE COURT: We'll be in recess until 12:15.

MR. THOMAS: Thank you, Your Honor.

(Short recess.)

THE COURT: All right. Are we ready to continue, Mr. Thomas?

MR. THOMAS: Thank you, Your Honor. Housekeeping matter. You had asked me if 113 had been admitted, I misinformed the Court, I thought it came in under Mr. McCall. It did not. I'd like to move it now, Your Honor.

THE COURT: Any objection?

MR. CLARK: I'm sorry. Which exhibit is that?

THE COURT: 113.

MR. THOMAS: 113. That's the CVS provider manual from 2013.

MR. CLARK: No objection. No, sir.

THE COURT: Admitted.

(Government's Exhibit 113 was received into evidence.)

MR. THOMAS: Thank you.

BY MR. THOMAS:

Q Mr. Newkirk, I've got from my notes pursuant to a couple of my questions of you earlier on direct that it can become evident to a PBM when a pharmacy is utilizing marketers through several telltale signs like a rep number on a claim, sorry, on a prescription or geographically disbursed claims. Can you offer the Court any other additional telltale signs that would indicate to a PBM that a pharmacy is utilizing third party marketers?

A Besides the obvious, a rep ID on a hard copy. The geographical, perhaps, the volume of compounded prescriptions, you know, that would be an indicator for sure.

Q And you're aware that in this case the defendants were marketing to at least in some instances Tricare patients. Correct?

A That's my understanding.

Q And that the Tricare claims were coming in from a relatively widely disbursed geographical range. Correct?

A Correct. Tricare members are all over the country and the world.

Q Would it be fair to say that ESI, who's the Tricare PBM, could at least to some degree been put on notice that the

pharmacies were utilizing third party marketers for Tricare patients?

A I don't see how they wouldn't know.

Q Did ESI treat Tricare differently than other payors?

A They treated them as a plan sponsor and they designed the Tricare, you know, benefit along with Tricare. And, you know, the compound benefit design was, you know, to my knowledge specific to Tricare.

Q We talked about the cost exceeds max and the overrides. That might be one difference, right, between Tricare and the commercial payors. Correct?

A Yeah. You know, any plan sponsor can, you know, create whatever plan parameters they want to, you know, put in place for a compound benefit. Tricare's plan design was, you know, pretty much a wide open benefit except for that, you know, at this point I would consider it a soft edit at $1,000, and then after that, there really was no stopping the claim.

Q Can you offer the Court as we sit here today any other matters that you're aware of that would differentiate Tricare from the commercial payors?

A Not that I can think of, no.

Q Is it fair to state that due to the cost exceeds max and the overrides that ESI, of course, was aware of the compound prescriptions that were coming in to ESI and being paid?

A Absolutely. I mean, of course, they know, that's their job, you know, they process the claims, and they pay them at the point of sale, and they know how much the claim is processing for and for who and for whom.
Q That was realtime. Correct?
A Correct.
Q So, you know, the people were literally picking up the telephone and talking to ESI reps to get the override. Correct?
A Yeah. There was no other way, if you bill a compound claim for $2,000, and the ingredients add up to that, it's a hard reject until you call Express Scripts and talk to somebody there, and go through the process to have it overridden. They were, you know, it's a very fast process. And to my knowledge, I do not know of one claim that was ever turned down.
Q And it's fair to state that ESI knew full well that the volume of compound claims that were coming in and at what amount because they were approving them?
A Absolutely. The volume and the cost.
Q Realtime?
A Realtime.
Q Let me ask the same question as it relates to CVS. You'll recall that Mr. McCall's testimony, and he's the CVS Caremark representative, there was a 72-hour compound script

review process at CVS Caremark. Do you remember that testimony?

A I do recall that.

Q So, is it fair to say that's kind of an analog to the Tricare, that CVS Caremark knew full well what the volume was that was coming in, what the claims looked like, they were doing realtime review of those claims coming in. Correct?

A They're a pharmacy benefit manager, that's what they specialize in, the processing and paying of claims. And, you know, Steve McCall even went into further detail. They had a compounding expert he said reviewing all of these claims within 72 hours. I don't know how they would physically do that, but, yes, they have the claims, the data, it's there.

Q So, is it fair to say that the pharmacy benefit managers were managing the pharmacy benefit for the payors in this case?

A Yes. That's their job.

MR. THOMAS: Thank you. No further questions on cross.

THE COURT: On direct you mean? Okay.

MR. THOMAS: I'm sorry. On direct, Your Honor.

THE COURT: Okay. That's what I thought. Why don't we go ahead and take our lunch break. It's about 12:30. Why don't we be in recess until 2:00 p.m. And I guess, Mr. Clark, at that point you're going to begin your cross-examination?

MR. PIPER: Judge, he is, but I think other defendants are going to cross as well.

THE COURT: Oh, are they. Okay.

MR. WALDEN: Yes, Your Honor.

THE COURT: Well, then, why don't we go ahead and still take our lunch break until 2:00, then we'll have other defendants first, and then let the government go.

All right. We'll be in recess until 2:00 p.m.

(Luncheon recess.)

THE COURT: All right. Who's next?

Mr. Walden.

MR. WALDEN: I believe I am, Your Honor. Thank you.

THE COURT: Okay. Mr. Newkirk, I'll remind you, you're still under oath, of course.

THE WITNESS: Thank you.

THE COURT: Go ahead, Mr. Walden.

CROSS-EXAMINATION

BY MR. WALDEN:

Q Mr. Newkirk, I represent Michael Chatfield. Of course, we've met before and we've spoken before. Right?

A Correct.

Q Okay. There are a couple of things that you said on your direct that I want to make sure that I'm clear on. The first thing that I want to talk about is this average wholesale price. And I believe that you said that the

manufacturer is essentially involved in setting what the AWP is. Correct?

A Correct. The manufacturer or whoever is, you know, packing the drug, the pharmaceutical company, they set the price of the AWP.

Q And there is a difference between a manufacturer and a compounding pharmacy, right, they're not the same?

A Absolutely. A compounding pharmacy is not going to have anything to do with setting the price of a drug.

Q So, the manufacturer makes sets of chemicals and the compounding pharmacy all they do is just mix them together. Right?

A Correct. They purchase the chemicals and.

Q You talked with Mr. Thomas a little bit about these preprinted prescription pads. And you said they were very commonly used especially in 2014 and 2015. Correct?

A Correct.

Q Even though a formula is preprinted, it can still be edited by the doctor. Correct?

A Correct. Yes.

Q Did that happen with some frequency in your experience?

A It absolutely can. The physician is fully able to, you know, sometimes the strengths of -- you'll have five different chemicals written down and there is no strength.

So, the physician would need to enter, you know, two percent or three percent, depending upon their knowledge.

Q And if they were already written down, could the prescriber edit the strength?

A Yes. They just cross it out and write in the new strength.

THE COURT: Let me ask a question. And I'm sure it's going to probably -- I won't hold it against any one of you if you laugh because I've already admitted I flunked high school chemistry. But what I do remember from high school chemistry is we had this periodic table that I thought I understood this is to the best of our knowledge this is every substance known to man.

THE WITNESS: Yeah. Well, I mean, a drug is a chemical entity that causes a, you know, physiological effect in the body.

THE COURT: This is what I was trying to ask you. In their purest most unadulterated form, any chemical known to man is on the periodic table. Right?

THE WITNESS: In combinations of the different elements in order to make it. Correct.

THE COURT: That's it. That's what I was trying to ask you. So, in one sense, any drug, any drug is compounded in a sense unless you are, unless it's being administered in its purest unadulterated form directly from the periodic

table, it is a combination of chemical, of substances that are on the periodic table that have been shown over time to have beneficial effects if ingested by human beings. Is that a fair definition of what a drug is?

THE WITNESS: In proper dosage, yes.

THE COURT: Okay. Go ahead.

BY MR. WALDEN:

Q And I just want to -- this has previously been admitted, this is just one of Michael Chatfield's prescriptions, Mr. Clark, just to make sure that we're clear with what Judge Mattice was talking about. So, what's on the screen is examples of compounding formulas. Correct?

A Correct.

Q So --

THE COURT: Each of those things, Fluticasone, that is what I'm going to call a drug that consists of certain chemicals that are put together in certain, you know, proportions. But it's chemicals -- Fluticasone is a combination of chemicals listed on the periodic table put together in specific proportions. Is that fair?

THE WITNESS: In a broad sense, yes, absolutely.

BY MR. WALDEN:

Q So, Fluticasone is something that's going to have various combination of these elements bonded together as the judge said. Right?

A Correct.
Q But Fluticasone mixed with, I'm going to try to pick one that's easier for the court reporter to spell.
A Gabapentin.
Q I'm going to go with Tranilast, T-r-a-n-i-l-a-s-t. Tranilast is not combining with Fluticasone to make a new substance, it's a mixture, so sort of like you pour salt and pepper together, it doesn't make something new, it's just a combination of both?
A Correct. They're both going to have a pharmaceutical effect and they could be, you know, different, one could be a steroid, one could, you know, do something completely different, an antihistamine, you know, whatever the pharmaceutical effect of that drug does not change when you make it into a compound. You're looking to get multiple effects at the same time.
THE COURT: Well, okay, so each of these, for instance, scar cream is a compound of compounded chemicals or elements. Right?
THE WITNESS: Correct.
THE COURT: Okay.
MR. WALDEN: Does that help Your Honor?
THE COURT: Yeah. I think so. It's been a long time since I was in the 10th grade. It's not going to do me any good anyway. I already got my F, so.

MR. WALDEN: Your Honor, if I was good at chemistry, I probably wouldn't have gone to law school.

THE COURT: Yeah.

BY MR. WALDEN:

Q While we're on that subject, I'm going to jump around just a little bit. We were talking about -- so, we were talking about how these forms can be edited. So, a prescriber could remove one of these ingredients from the formula. Correct?

A Correct. They could cross it out. They could change a strength. A pharmacy could bill, you know, say a physician in the pharmacy, they pick a neuropathic transdermal cream, they pick neuro one, they bill that off to the insurance company and say Gabapentin is not covered, so, it's blocked. The pharmacy then could say, all right, let's see if we can get something else that is covered. And they would go ahead and, you know, talk to the doctor and swap it out. The pharmacy could also just accept payment for what is covered and not be paid for the Gabapentin, then it becomes more of, you know, a financial decision and does it makes sense.

THE COURT: Okay.

BY MR. WALDEN:

Q Are there any reasons why these preprinted pads might actually be beneficial for a pharmacy to use as opposed to a regular handwritten script?

A Clarity. You know, cut down on errors, medication errors, which with handwritten prescriptions are notorious. They spell out an ingredient and, you know, Ketamine looks like Ketapropen sort of, so they fill the wrong chemical. They write one percent and the physician writes 1.0 percent, which is an absolute do not do that in the pharmaceutical world. You never have a zero after a decimal point because you won't see the decimal point and you'll fill 10 percent could, be dangerous.

THE COURT: Deadly?

THE WITNESS: Absolutely.

BY MR. WALDEN:

Q Is it more likely for those errors to occur -- I'm going to call them handwriting errors because the issue is the pharmacist can't read the doctor's handwriting, is that essentially what you're saying?

A Essentially, yes. I mean, it's a long standing joke, you know, doctor's handwriting.

Q Is that more likely to occur when there is a customizable medication such as a compound versus something that's more common like Lipitor which --

A Well, yeah, it's more likely because you have to, you know, there might be six ingredients that a physician has to write, you know. Now, you're writing instead of one drug, you're writing six drugs.

THE COURT: Well, I mean, the Lipitor, for example, just comes to the pharmacist in its already combined form, there is nothing to do except measure, count the pills. Right?

THE WITNESS: Pretty much. Pretty much.

THE COURT: All right.

BY MR. WALDEN:

Q Which brings me right to my next point, Judge. Compounds are customized medications. Right?

A Correct.

Q They are -- so, Lipitor when Pfizer or whoever it is makes Lipitor, they're making thousands of pills at a time in a factory. Right?

A Correct.

Q How are compounds made? Are they made all at once in batches or are they made per script?

A Depends upon the volume at the pharmacy, sometimes they will make small batchers if they know they're going to have, you know, so many of neuro one creams in a day, they might premake on a small scale because you have to deal with, you know, beyond use dating on a compound. They're only good for so long before they expire. Ideally everything is made on an individual basis, but if you have 10 of these coming in or you have 10 prescriptions coming in, you're going to make a larger batch.

Q You've testified that you're familiar with how the software program for billing to a PBM works. Right?
A Correct.
Q And sometimes you get reject codes in compounding. Correct?
A Correct.
Q And those can be for various reasons. Right?
A Yes.
Q What are some of those reasons?
A It could be exceeding the cap, you know, there could be a hard cap on the cost of the drug, you know, $500 cut off. There could be an ingredient, so you have 10 ingredients and two are not covered, so it will reject and tell you the two that are not covered. And then as a pharmacy you need to deal with that.
Q All right. Let's talk about some other reasons. So, let's say that I have a prescription that has a refill. I fill a 30-day supply and I come back in two days later and try to get my refill. What's going to happen then?
A Chances are it's going to reject for a refill too soon. Chances are. And most insurance companies have utilization of about 75 percent is the standard. So, if I come in January 1st and fill a prescription for a 30-day supply, if I go in on January 21st and try and refill it, it's going to reject refill too soon in that instance. If I get it

filled on January 22, it will shoot right through.
Q So, it doesn't have to be the full 30 days?
A It does not. But, you know, there is -- don't assume that every plan has 75 percent utilization. Some will have 60 percent utilization, some will have 50 percent utilization. Back in, you know, Medco auditing there were plans that had no restriction, so theoretically a person could get, you know, one prescription with 11 refills, they could come in every following day if the plan design isn't to reject it for a refill too soon, it will go right through and pay.
Q And if it's designed for a refill too soon, is there a way to override that?
A It depends upon the plan and the PBM, so.
Q Can you give us some examples of that like, for example, is there a lost or stolen override in some plans?
A You know, the best example I can give you is first hand knowledge of Medco because of the auditing. So, they had three overrides you could use at the pharmacy, you know, the pharmacy could input an override for a lost med, which was an 03 override. You just enter 03 and if the plan sponsor covered lost meds, it would go through and cover it. If they didn't it would reject, it's not -- that was vacation, 03 is vacation, sorry let me correct that. 04 is lost med. Usually almost never worked. If you lost your medication, you're pretty much out of luck. The 05 override was for a therapy

change. So, if you're getting one daily and then the doctor wants you to go up to twice a day, you get a new prescription for 60 is a 30 day supply, you're 10 days out, it rejects for refill too soon, you can use an 05 override for a therapy change. That was Medco. Many of the PBMs an early refill is a hard reject and you have to call the insurance company and explain what's going on and whether or not they will allow the override is determined by the insurance company.

THE COURT: Let me ask you an example. For instance, a lot of prescriptions are use as needed. I mean, I guess, I mean, basically, which tells me physicians leave it up to the patient how much or little to use at any point in time. So, I mean, they give you, you know, some quantity the first time you pick it up, you know, a tube of something, come back the next day, you know, you got six refills, I used it all last night, you know. And, I mean --

THE WITNESS: It's a great question and there is a progression there. You know, early on at Medco when you dispensed a topical for 100 grams, use as directed, we audited based upon refill history. If it got filled every 30 days, we weren't concerned. If it got filled every 90 days, then we'd say, okay, that's too much, we're going to cut it back.

THE COURT: What if it said use as needed, the physician wrote use as needed?

THE WITNESS: Early on we would audit based upon

utilization, on history. After, you know, Medco during this time period, use as needed wasn't really accepted. You had to get clarifying directions one to two grams twice a day, that's four grams times 30. Exactly.

THE COURT: And the word went out to physicians don't write use as needed, you know, prescriptions?

THE WITNESS: When they don't --

THE COURT: Well, no, I mean, if you said you didn't accept scripts that said use as needed, I mean, you had to get that word to the doctors and, hey, doc, don't write a use as needed because we have no idea what you mean by that?

THE WITNESS: Right. Well, you'd only have to be audited a couple of times by an insurance company to say --

THE COURT: Your patients are going to complain?

THE WITNESS: We need directions. So, you know, if you get use as directed, you're going to call the doctor, I need specific directions so I can do the calculation.

THE COURT: Okay.

BY MR. WALDEN:

Q Taking the judge's point one step further. Do these compounds typically expire quicker than maybe a normal prescription that you get from a retail pharmacy?

A Typically, they do, yes.

Q How quickly do they usually expire or do you know?

A Offhand, it's all based upon the guidelines for

compounding, and it's whether it's water based or not water based, and usually, you know, 60 days, 90 days, something in that range.

THE COURT: Do they not put sort of preservatives in?

THE WITNESS: They do not.

THE COURT: They do not?

THE WITNESS: No.

THE COURT: At all?

THE WITNESS: Not at all.

THE COURT: Okay. Well, I mean, pharmaceutical manufacturers do put preservatives in their medications sometimes?

THE WITNESS: Sometimes and sometimes not, you know, a lot of times they're preservative free.

BY MR. WALDEN:

Q And sometimes that's actually a reason for a compounded medication, right, because someone may be allergic to a preservative?

A Exactly.

Q I asked you to review some pharmacy patient files in preparation for your testimony today. Do you remember that?

A Yes, I do.

Q And did you review those?

A I did.

Q I'm going to call up on the iPad what is going to be Collective Exhibit 20 for Mr. Chatfield. I believe it included 92 different patient files. We're not going to go through all of those because that would be quite tedious, but you have gone through all of those. Correct?
A Correct.
Q This is Jacob Burgess. These were provided by the government in discovery and they were patient files from Willow Pharmacy. My version is redacted, but we'll -- I believe we can still use them for our purposes today. So, the first set of documents in these forms is usually this universal claim form. Right?
A Yes.
Q Can you kind of describe what this is?
A It's a standard claim form that could be sent off to an insurance company that lists all of the different ingredients, the quantities of each ingredient, and it even has, it has the ingredient cost on there also.
Q All right. Also contained in these files were the prescriptions themselves. Right?
A I believe so, yes.
Q And then there were also pages that looked like this. Correct?
A Correct.
Q Can you explain what -- because this is a lot of

gibberish to me, but can you explain what these pages mean to you generally?

A Generally, this looks like the information that is being submitted for each of the fields required to transmit a claim and/or the response back from the pharmacy.

Q All right. So, for example, the additional message information at the top, from PBM. So, that's a message from the PBM to the pharmacy. Right?

A Correct.

Q That says manual DUR necessary. What does that mean?

A Manual DUR is drug utilization review. So, there has been some sort of edit that fired that the pharmacy is going to have to use their professional judgment in order to override this in order to process the claim.

Q All right. So, this code is a, it's a reject code and the pharmacy has to override it if they see it?

A Yes. And it looks like, if you scan down, you'll see the reason for the service code is a drug drug interaction. So, more than likely, you know, when this claim was billed, they're on, the member is on another drug that either has the same drug in it or a drug in the same class. So, it's firing an edit there is a drug drug interaction. And at this point the pharmacist would review the history and if needed call the physician and use their professional judgment

in whether to override this or not.
Q And, actually, I think there was an override page for almost every prescription that I asked you to review. Right?
A Yes.
Q And correct me if I'm wrong, the prescriptions that I asked you to review were Blue Cross Blue Shield patients specifically?
A If I recall, yes.
Q And, also, and more than that, Blue Cross-Blue Shield patients who received prescriptions from Willow Pharmacy in May of 2014?
A That sounds correct, yes.
Q Okay. Did you ever see in this additional message information a reject code that indicated that a prescription was being refilled too soon?
A I did not see a reject for a refill too soon.
Q Did you see any override contained in any of the data that would show that the pharmacist input a lost or stolen override code?
A I did not see that.
MR. WALDEN: Just a moment, Your Honor.
(Brief pause.)
MR. WALDEN: Your Honor, I need to move Collective Exhibit 20 into evidence.

THE COURT: Any objection?
MR. CLARK: No objection, Your Honor.
THE COURT: Admitted.
(Defendant Chatfield's Exhibit 20 was received into evidence.)
MR. WALDEN: That's all of the questions I have. Thank you.
THE COURT: Who's next? Any other defendants?
MR. HOBBS: No, Your Honor.
THE COURT: Then, Mr. Clark, cross-examination.
MR. CLARK: Thank you, Your Honor.

CROSS-EXAMINATION

BY MR. CLARK:

Q Good afternoon, Mr. Newkirk.

A Good afternoon.

Q Mr. Newkirk, my name is Frank Clark. Mr. Piper and I represent the United States in this matter. You and I have not spoken I don't believe. You're currently in Birmingham. Is that right?

A No, that's the corporate address for Pharmacy Compliance Consulting. I live in Pittsburgh.

Q You live in Pittsburgh. I understand. Now, sir, you have reviewed the testimony of Steve McCall, is that correct, before your testimony today?

A I have read it, yes.

Q All right. Who else's testimony in this trial have you reviewed?
A Was there an Express Scripts testimony?
Q So, you reviewed the testimony of someone from Express Scripts?
A If I recall correctly.
Q Well, did you review anyone else's testimony besides Steve McCall?
A Not that I recall.
Q All right. So, just one individual's testimony is all you've reviewed before in preparation for your testimony today?
A As far as I recall.
Q Okay. Would you recall reviewing someone else's testimony? Is that something that you would have done and then forgotten about?
THE COURT: Do you think you reviewed anyone's testimony that was from Express Scripts because as I recall Mr. McCall was from CVS Caremark?
THE WITNESS: Right. Then that would be all.
BY MR. CLARK:
Q Okay. So, Mr. McCall from CVS Caremark testimony is the only witness' testimony that you have reviewed from this trial?
A As far as I recall, yes.

Q Okay. I understand you said as far as you recall. You would recall reviewing someone else's testimony? That would be an important fact in preparation for your expert testimony here today. Correct, sir?
A Correct.
Q So, I'm not trying to ask a trick question. Is there someone else's testimony that you have reviewed?
A I would have to say no.
Q Okay. Thank you. First off, compounded drugs I think everyone agrees, there is at least a limited legitimate purpose for a compound medication. Correct?
A There is a -- what do you mean by "limited"?
Q They're not always appropriate, but there are certain limited situations in which I think everybody can agree they're appropriate?
A Yes. Appropriate, yes.
Q Okay. Let me ask you this. Is the FDA's drug approval process important?
A I would imagine, yes, it is. Yes, it is.
Q Okay. And it involves the vetting of drugs for a whole host of reasons. Correct?
A Correct. Right.
Q And it's necessary -- would you agree that it's necessary that these drugs that are not yet on the market go through a pretty rigorous approval process before they become

commercially available. Would you agree with that?
A Yes.
Q Okay. And what are some reasons that that's necessary and a good idea that we require these drugs to be vetted before they become available?
A Well, safety reasons.
Q Absolutely.
A Efficacy.
Q Absolutely. Any other reasons?
A You don't know in many of these drugs, you know, down the road whether or not they're going to cause an adverse effect. So, multiple reasons for the FDA to take it through clinical trials to establish, you know, whether a drug even works.
Q Right. We've used the example Lipitor a lot today. Before Lipitor ever hit the market, it had to go through this very rigorous evaluation and testing process, didn't it, sir?
A Correct.
Q Any idea how long that takes?
A Usually, I mean, upwards five, 10 years typically.
Q Any idea how much it costs?
A I've heard from big Pharma two billion dollars.
Q You would agree with me, and I think I heard in your direct examination, compounded pharmaceutical is a way around that, isn't it, sir?

A They are exempt from the FDA approval process.
Q Right. And a compounded drug has not been subjected to the testing, to the screening, to the gatekeeping function that that's designed to protect everybody against? You would agree with me on that, wouldn't you, sir?
A Yes, of course.
Q And that's why compounded medications are supposed to be used in very narrow, very limited, and very unique circumstances, aren't they, sir?
A Well, if a physician prescribes a compounded drug for a patient, that's within their right to prescribe it.
Q I'm not talking about what someone has a right to do. I'm talking about you're a pharmacist and you know the purpose and the role that compounded pharmaceuticals play, do you not, sir?
A I do.
Q And because compounded drugs have not been subjected to this battery of tests to make sure that they're safe, they're effective, it's important that they be used in very limited, specific and unique situations, isn't it, sir, or would you not agree? If you don't agree, that's fine, but do you agree with me?
A In that aspect, no, actually, I disagree.
Q Okay. So, you think that the mass prescribing of compounded pharmaceuticals is appropriate?

A I didn't say that either.
Q Well, do you think that the mass prescribing and sale of compounded pharmaceuticals is appropriate?
A If utilized correctly, yes.
Q Okay. Do you agree with me that it is important that before a compounded drug is prescribed to a patient other treatment options should be tried first to see if they're ineffective or adverse to a patient's health?
A If there are other treatment options.
Q You would agree with me, though, that a compounded drug should not be prescribed until other treatment options have been tried to see if they are either effective or adverse to a patient's health?
A In a sense I would disagree with that statement.
Q All right. So, you would not agree with the statement that compounding -- compounded drugs provide treatment options alleviating pain, suffering and long occurring infections, just to name a few, where other treatment options have been ineffective or adverse to the patient's health. You would not agree to that limiting statement?
A Repeat that again.
Q Yes. Compounded benefits provide prescription treatment options alleviating pain, suffering, and long occurring infections, just to name a few, where other

treatment options have been ineffective or adverse to patient's health. Do you agree with that, sir?
A I could agree with it.
Q You could not agree with that?
A I said I could agree with that.
Q I'm not asking you could you. Do you agree with it, sir?
A The way you read that, yes.
Q Okay. So, you would agree with me that's a statement that you had made yourself, is it not, sir?
A Yes. I wrote that.
Q Right. So, let me make sure I understand. Is it not important that other treatment options be tried first before we go to compounded options?
A Depends upon the physician. You know, if you want to treat pain, you know, a physician could go straight to opiates or perhaps they might want to try a compounded pain cream.
Q Let me ask you this. If you had this to write again, would you delete this limiting sentence, where other treatment options have been ineffective or adverse to the patient's health because that's what you said?
A I wouldn't change that.
Q Okay. So, it is at least something that should be considered before a compounded drug is prescribed. And by

something I mean the issue of whether or not that another treatment option has been considered before going directly to a compounded pharmaceutical?

A That's going to be up to the physician.

Q But it's something that you believe should be considered when you wrote this, did you not? And you're a pharmacist.

A I think I'm interpreting the statement differently than you.

Q Okay. Well, tell me how you're interpreting the statement, where other treatment options have been ineffective or adverse to the patient's health.

A I don't see how that says that they have to try other treatment options first.

Q Okay. Sir, is a two-minute telephone conversation between a nurse practitioner and a patient he or she has never met or seen before sufficient for the nurse practitioner or doctor to make a legitimate objective determination as to whether a compounded pharmaceutical is appropriate for that patient?

A It would be up to the nurse practitioner.

Q Is it possible for a nurse practitioner to make that determination if the nurse practitioner never speaks with the person or sees the person?

A I think that would be difficult.

Q It would be difficult. It's important that a pharmacy collect a copay. Is that correct?
A Correct.
Q As a matter of fact, it's required that a pharmacy collect a copay. Isn't that correct?
A Correct.
Q It's required by PBMs under the terms of most, if not all, PBM contracts. Is that correct?
A The way I read, yes, it is contractually required.
Q And it's required by law often times, is it not?
A That would be a law question, but I would imagine it could be addressed by state laws.
Q Right. You're familiar with some state laws concerning copays, are you not?
A Yes.
Q Right. You're aware that in many instances failing to collect full copay from the customer is fraud, is it not, sir?
A It would depend upon the state law, yes.
Q And it is a requirement that the copay be paid, isn't it, sir?
A It is. If it's not collected, it would be a discrepancy for that claim.
Q Right. And fraud?
A Well, I don't know that because --

THE COURT: State law, is that what you're asking, because, I mean, I mean, I just don't know. Are there state laws that define failure to require a patient to pay the full amount of copay, that is defined as fraud under some state law?

MR. CLARK: Let me ask him if he agrees with the statement.

BY MR. CLARK:

Q Would you agree with the statement that some states such as Florida have laws requiring copays to be collected?

A I believe there is a statute in Florida that requires under Medicaid for copays to be collected.

Q Would you agree with me that waiver of the copay is considered fraud and a violation of state law?

A In the state of Florida for a Medicaid claim for the pharmacy, yes.

Q Let me show you a document. Do you recognize this document?

A Yes, I do.

Q Who's the author of this document?

A I believe me.

Q Okay. That's you and Christopher Gruber. Who is Christopher Gruber?

A He's my partner.

Q And this is advice that you're sending out to

pharmacies that pay you to provide consulting services. Correct?

A Correct.

Q Right. And you would agree with me this says PBM require pharmacies to collect 100 percent of the copay at the point of sale. You'd agree with that statement. Correct?

A I would agree with that.

Q You made it. That's correct. Let me show you another document that's been introduced as Government's Exhibit No. 6. This is an e-mail that's been introduced. Let me show you number three. I'll represent to you it's been testified this is from a marketer to other marketers who worked for him. Be sure that the patients know they will never pay more than a $15 copay. Even if their insurance EOB says you owe $$$, they do not owe that. If the insurance pays for the cream, Willow Pharmacy will eat the rest because there will be enough to cover the cost. You'd agree with me, sir, that is prohibited by PBMs, and under your words, is considered fraud. Is it not, sir?

A For the pharmacy, yes.

Q For the pharmacy to eat, to "eat the rest" because the pharmacy is required to collect a copay, sir?

THE COURT: Wait a minute. Is that -- okay. Maybe is that what that says, number three?

BY MR. CLARK:

Q Did I read it correctly, Mr. Newkirk?
A I mean, it's basically, you know, they're saying they're self limiting the copay to $15, the pharmacy is doing this. And if the copay is higher, Willow Pharmacy is either going to cover it or just waive it.
THE COURT: And you think that the entire Paragraph 3 refers to the copay?
THE WITNESS: Never pay more than $15 copay. I think that refers to the copay.
THE COURT: What about the rest? What about the two succeeding sentences?
THE WITNESS: Even if their insurance EOB says you owe money, they do not owe that. I'm not sure what that refers to.
THE COURT: I'm not either. And, I mean, I don't know if you can answer it or not.
THE WITNESS: I don't know why the EOB -- I think I view an EOB, an explanation of benefits, that comes later.
THE COURT: Okay. I guess I'm going to let this go, but, I mean -- well, maybe I shouldn't since I'm the tryer of fact. But, I mean, in my experience, I get explanation of benefits from my insurance company. And let's say it's usually -- actually, this is confusing because what I think is my explanation of benefits comes usually from my insurer, and I get something from my pharmaceutical carrier that I referred

to earlier that, I guess, is an explanation of benefits. I can't remember if that's what they call it. But, typically, in my experience, I've always paid my copay. It's a pretty minimal amount up front, you know, 15 bucks, 30 bucks, something like that. Now, sometimes, I will get later a statement saying you owe this, but it's not my copay that I didn't pay, it's because there is a deductible that's been unfulfilled or something like that.

THE WITNESS: Right.

THE COURT: And so, that's where I'm confused. And maybe you two can clear that up for me. I mean, what I'm reading, the way I'm reading Paragraph 3 is that, okay, you probably have to pay up to a $15 copay, but then you may get an explanation, you owe this. Well, in my experience, that could be for various reasons. And I don't know if that makes a difference legally or not. Can you -- okay. That's my question. I don't know if anybody can clear it up or not.

BY MR. CLARK:

Q You're familiar with insurance company billing and with respect to what portion a patient has to pay?

A Correct.

Q The insurance framework that Judge Mattice is talking about where there is a deductible and until you meet your deductible --

THE COURT: You have to pay. I mean, that's what

they always tell me, and by --

BY MR. CLARK:

Q That's correct. Two types -- generally speaking you'd agree with me there is two types of insurance plans, there is the deductible plan where you have to pay the entire cost until your deductible is met, then you pay a percentage?

A Correct.

Q That's one type. The other type is where you probably pay either a smaller premium or higher premium, but you pay a copay and then you don't pay anything else?

A Correct.

Q Correct. Okay. So, you'd agree with me that copay either in the insurance world and in the vernacular, copay refers to what a patient is going to have to pay out of their pocket. Correct?

A Correct.

Q Okay. So, you'd --

THE COURT: But does that include what I'm referring to, what I'm calling a deductible?

MR. CLARK: I think it's two different things, Your Honor. We throw the term copay around. My understanding and I'll ask Mr. McCall if he agrees with me --

MR. PIPER: Mr. Newkirk.

MR. CLARK: I'm sorry, Mr. Newkirk. The copay doesn't really come into play if you have an insurance plan

involving a deductible. Copay is for a different type of insurance plan where a copay is all you're going to pay for a particular service.

THE COURT: Now, by the way, now, okay, and I'm talking about my experience, okay.

MR. CLARK: Yes, sir.

THE COURT: I pay copays regularly and then I still am sometimes called on to meet my deductible before my insurance carrier pays. Now, if I've been making foolish insurance decisions all of these years, I presume I'm not alone, but, I mean, you know, I mean, that has been my experience.

MR. SCHWARTZ: And, Judge, from a personal standpoint, I have to disagree with Mr. Clark because I have a Blue Cross plan and I have copays that I have to pay for certain medications, zero copay for others. And I still have a $500 deductible that I pay on myself and then $1500 family total deductible that we also have to meet. So, I have deductibles to pay as well as copays on visits, procedures and --

THE COURT: Okay. Well, see, I have Blue Cross, too. And, I mean, I guess, I'm just -- really, now, I am wondering if I've bought the wrong insurance plan all of these years, but at any rate. What I guess what I'm more interested in for purposes of today is defining the term copay and what

all that that might entail.
BY MR. CLARK:
Q Right. And it's important that the patient pay the copay. Is this correct?
A That's -- in a general sense, yes. The copay needs to be collected from the pharmacy.
Q Right. By the pharmacy. Correct? The copay needs to be collected by the pharmacy?
A Correct, by the pharmacy.
Q Not from the pharmacy. Okay. It needs to be 100 percent. Is that correct?
A In the audit world, in the end, yes, if you have not collected 100 percent of the copay and that claim is audited, it's a recoupment.
Q Right. And a pharmacy is not allowed to eat any portion of the copay. You would agree with that?
A I would agree with eating, yeah. Yes.
Q Okay. And what is the purpose, do you know, behind requiring a patient to pay even a small copay?
A It gets them to have, you know, a part in the --
THE COURT: Skin in the game.
THE WITNESS: Skin in the game. That's what I was looking for. Thank you.
BY MR. CLARK:
Q So, if someone else makes that copayment on their

behalf, it defeats the whole purpose behind requiring the copay, does it not?

A It can. Yes.

Q And, in fact, it does, if an interested third party makes the payment, does it not?

A Well, I look at manufacturer's coupons and the reduction of copays by manufacturers. I can't get over how, you know, this affects the skin in the game. And it's done on a daily basis across the country all day long.

THE COURT: Well, let me -- okay. In the course of this trial we've made this observation that, and I think I've made this observation today, you know, I mean, to a certain extent, the interjection of insurance into a free market system detracts from what, for lack of a better -- well, I mean, the economists call moral hazard. Okay. You make decisions based upon relative benefit versus, you know, detriment to you and so forth, so, insurance -- and, you know, the policy reason for requiring a copay is to ameliorate at least to some extent the problems associated with, you know, moral hazard in a free market. Now, that's a very abstract way to state the problem. I mean, is that your understanding of what the underlying policy foundations for this are?

THE WITNESS: I mean, the underlying copay is to have skin in the game.

THE COURT: Okay. Yeah.

THE WITNESS: And copays have gone up.

THE COURT: That's a better way to put it, but I tried to put it in a little bit more eloquent terms. Okay. Probably failed. All right. Go ahead.

BY MR. CLARK:

Q As a matter of fact, you're familiar with -- let me -- you're familiar with CVS Caremark. Is that correct?

A Yes, I am.

Q You're familiar that CVS Caremark requires that the copay be collected from the eligible person. Are you aware of that?

A Their language, I think it is exactly that, the eligible member.

Q Right. Yeah. Provider must promptly collect from the eligible person the full patient amount. That means, in other words, again, this is another safeguard to make sure that the patient really needs and wants this medication?

A In a large sense for the skin in the game.

Q Right. That's why it doesn't say provider must promptly collect from anybody with money the full patient pay amount?

A But, you know, once again, you know, you have a copay of $100 and you run a manufacturer's coupon, it pulls it down to 20.

Q I understand.

A Is that the eligible member?
Q I understand you keep going back to the manufacturer's coupon, but it says here that it must be collected from the eligible person. Correct?
A Correct.
Q Right. Full amount. Correct?
A Correct.
Q Catamaran says the same thing. Are you familiar with that?
A I am.
Q They actually say, they actually say provider must charge the member?
A Correct.
Q Okay.
A Provider would be the pharmacy.
Q Right. And Express Scripts goes a little further, they actually set forth why it's important to collect a copay from the patient, don't they?
A I would assume they are.
Q Okay. Well, you're familiar with the manual?
A Yes, I am.
Q You testified about your familiarity?
A Yes, I'm very familiar.
Q And would you agree with this statement in the ESI manual, Section 2.3 that copayments are a critical benefit

design tool that can sensitize members to the cost of their medications and encourage members to seek out less expensive medications that are --

THE COURT: That's a great statement of what I just tried to express in a less artful manner. Okay.

MR. PIPER: I thought yours was artful, Judge.

THE COURT: Does everyone in the courtroom agree that mine was better than everybody else's?

MR. PIPER: I'm kidding, Your Honor.

THE COURT: I know. All right.

BY MR. CLARK:

Q And you'd agree with the rationale behind this, would you not, sir?

A Yes. In a broad sense, this is the design of copays to do this.

Q Right. And that's why a pharmacy is not allowed to eat a copay?

A Correct.

Q When a church, to use your analogy, I think, you used on direct, when a church volunteers to give an individual money to pay their copay, what is that church's motivation?

A Health care, I would imagine.

Q Right. Would you ever advise your pharmacies that pay you for consulting advice that it's okay to send a marketer to meet a customer at the Red Bank Post Office and

give them cash to buy money orders to send in for their copay?
A Would I advise that? No.
Q Okay.
MR. THOMAS: Objection, Your Honor, far beyond the scope of direct.
MR. CLARK: I don't think it is at all, Your Honor.
THE COURT: Well, no, I'm going to overrule that objection.
MR. CLARK: Thank you.
THE COURT: I think that the direct was designed to elicit -- I mean, that was a very concrete example, but I mean, overruled.
MR. CLARK: Thank you.
BY MR. CLARK:
Q The doctor or the nurse practitioner is a very important part of the prescription system, are they not, sir?
A Correct.
Q And as a matter of fact, they're one of, if not the most important gatekeepers in the process. Would you agree with that?
A They're one of the key gatekeepers, yes.
Q One of them. There are others, are there not, sir?
A Correct.
Q Right. But one of them being the pharmacist. Correct?

A Correct.
Q Right. And the pharmacist, assuming the pharmacist is operating independently, the pharmacist relies on the doctor or the nurse practitioner for both the necessity of the medication and the efficacy of the medication. Isn't that correct?
A Yes.
Q But you'd agree with me then that if the prescribing health care professional is compromised, the entire system breaks down, does it not, sir?
A It could.
Q If the prescriber has a financial or any other interest in prescribing other than medical necessity, that would be important, would it not, sir?
A It could be relevant, yes.
Q Right. Now, what was the --
THE COURT: Now, let's talk about. I mean, we've talked about that before. That may well be true, that in a perfect world the gatekeeper so to speak is totally independent financially and otherwise of, you know, that whom they're supposed to be regulating. Now, in the United States, for instance, publicly traded companies are required by the Securities and Exchange Commission, United States government, to have audits. And, typically, these people are audited by some of the wealthiest and most influential professional firms

on the globe. And, you know, I think that now they're called the big four accounting firms. They're for-profit institutions that get their fees from audits from, and they're huge fees, I mean, multi multi million dollars fees from companies who pay those fees.

And then the financial markets, according to the system, are supposed to, you know, rely on those audits by these, by these firms who are being paid by the companies whom they audit, you know, as the gatekeepers who they can rely on. So, I am just pointing that out, as an example, yeah, in a perfect world, any gatekeeper and let's, you know, I'm analogizing to, you know, certified public accounting firms in the United States, should be completely and totally financially independent of those whom they're supposed to regulate. I mean, it just doesn't happen that way, I mean, and that's just one example, you know. I mean, by the way, you know, in the same realm, law firms issue very expensive legal opinions to their clients who are selling their securities and the clients are paying those lawyers' fees for their so-called independent legal opinion, and then they go sell their securities based upon that.

So, I mean, I hear what you're saying, Mr. Clark. I do get that. But, I mean, it would be hard to point me to an absolutely pure system of that. Okay. And so, I want -- I'm not going to cut you off. You can question about that. But,

I mean, I'm just telling you, in my experience, pure systems of what you're talking about are pretty rare. And, I mean, you know, so, all right. Go ahead. I've made my point.

BY MR. CLARK:

Q You agree with me, certainly, that would be relevant, though, would it not, sir?

A Yes. It could be relevant how that is structured.

Q Right. But you'd also agree with me there is no discrepancy code for that. Is that correct?

A Correct.

Q So, certainly, there are things that are relevant for which there is not a discrepancy code?

A Relevant to who?

Q Relevant to whether the prescription is legitimate.

A Correct.

Q How many total discrepancy codes are there?

A Which PBM?

Q Well, in general terms, are we talking about hundreds and thousands or are we talking about --

A Twenty to 30 to 40.

Q Twenty to 30 to 40?

A Correct.

Q There is also no discrepancy code for fraud, is there, sir?

A Not that I know of.

Q Right. But, certainly, if a prescription was the product of fraud, you're agree with me that would be relevant as well, would it not?
A Yeah. They're going to --
Q Right. So, just because there is no discrepancy code doesn't mean that an issue is not relevant and material, does it, sir?
A Or, you know, to be investigated on the claim. Correct.
Q Exactly.
THE COURT: Well, okay. And, I mean, this is the crux of the testimony. I mean, you know, Mr. McCall testified as to what he, you know, based upon his background and experience he found relevant. The legal term is material. Mr. Newkirk from a little bit different background, little bit different perspective is what, you know, he has called discrepant. And those two things between what Mr. McCall was talking about and what Mr. Newkirk have talked about are different. They're coming at the thing from different perspectives.
And, obviously, I mean, different people may find different things and situations "material," but my job in deciding what is material is based upon an objective standard that covers if not everybody can agree to, that's what I decide a reasonable person would agree to would be material.

So, let's just -- I want to get that out on the table because that's what we're talking about here today. And I hear you two, you know, and this is perfectly appropriate, I mean, it's informative to me, but that's what -- the decision I've got to make is what an objective standard of materiality is. Okay.

MR. CLARK: Thank you, sir.

BY MR. CLARK:

Q Certainly, sir, a pharmacy, I believe you testified on direct examination can change a script?

A Correct.

Q But that is only in consultation with the doctor or nurse practitioner. Isn't that right, sir?

A Yes. The prescriber.

Q Right. The pharmacy or the pharmacist shouldn't be changing the script on its own?

A Correct.

Q Whether it's a lab tech at the pharmacy or whether it's the pharmacist, the pharmacy cannot do that. Correct, sir?

A Correct.

Q Neither can a marketer. Correct, sir?

A Absolutely not.

Q Okay.

A Or correct.

Q Are you aware of compounding pharmacies hiring

doctors to write scripts for their own compounds?
A Compounding pharmacies to hire doctors to write for the pharmacy employees. Is that what you're asking?
Q Are you aware of compounding pharmacies that pay doctors to write prescriptions for the drugs that they compound?
A No.
Q Have you -- you did not recall reviewing anyone else's testimony other than Steve McCall, so, certainly, you didn't review the testimony of a nurse practitioner named Michelle Craven. Is that correct?
A Just the -- I think there was -- I'm familiar with the name. I've looked at a document or two that she's come up.
Q Certainly. Though, you would agree with me that if she testified that she signed scripts at Mr. Wilkerson's insistence without communicating with the patient and without ever seeing the patient, that would be inappropriate, wouldn't it, sir?
A For her, absolutely.
Q Well, I understand you keep saying it's strictly on the doctor and the person inducing the doctor to do that in your mind bears no responsibility. Is that what I understand you to be saying?
A For a medical license, in my opinion, yes.

Q I'm not talking about medical license. I'm talking about someone -- I'm talking about -- you see nothing wrong with a person offering, I'll call it a bribe, you simply see something wrong with someone taking the bribe?
A No. No. The prescriber has the full responsibility when prescribing that medication.
Q You'd agree with me that there is no doctor patient relationship in the scenario I just presented to you with a nurse practitioner signing scripts at a marketer's encouragement and insistence without that nurse practitioner ever seeing or talking to the patient?
A In that scenario, it does not sound like that there is a doctor patient relationship.
Q Exactly. Because there is not one, is there, sir?
A In that scenario, it does not seem to be one. They may have a history. I don't know.
Q Right. Were you, in any of the documents that you reviewed, were you made aware that Candace Michelle Craven has pleaded guilty to a health care fraud conspiracy?
A With the documents, no.
Q Were you aware of that?
A I was aware of that.
Q You talked about the chart review of the Blue Cross Blue Shield patients at Karma. You don't know if Blue Cross Blue Shield knew that Ms. Craven was involved in a conspiracy

to commit health care fraud or not, do you, sir?
A I do not.
Q Because, certainly, Ms. Craven didn't tell them that, did she? Did she, sir?
A Apparently not.
Q Willow Pharmacy didn't, did they, sir?
A I would imagine not.
Q Nobody at Top Tier did, did they, sir?
A I don't think so that they were consulted.
Q So, certainly, Mr. Wilkerson didn't either, did he, sir?
A I would imagine not.
Q All right. Are you aware that Ms. Craven testified that others in the conspiracy used her stamp to authorize prescriptions without her knowledge?
A I was not aware of that.
Q Are you aware of a discrepancy that exists for unauthorized signature?
A I think that may exist in some of the manuals.
Q Certainly, it's inappropriate, is it not?
A Or marked it as invalid, something.
Q Certainly, whether there is a discrepancy or not, it's inappropriate, isn't it, sir?
A Yes.
Q Does it seem fraudulent to you, sir?

A If someone else signs a prescription, yes, that is a major issue.
Q Right. If the prescriber was involved in a conspiracy to commit health care fraud with the marketers, that certainly would be material, would it not, sir?
MR. THOMAS: Your Honor, objection.
THE COURT: What was -- restate the question again before you -- what was the question?
MR. CLARK: I asked him if the prescriber was in a conspiracy to commit health care fraud with the marketers, as Ms. Craven testified that she was, that would be material, would it not, sir?
THE COURT: What's your objection?
MR. THOMAS: My objection is that does not assume any facts in this case, we are hearing about the *United States versus Jimmy Collins.*
THE COURT: I think it probably calls for a legal conclusion, so objection sustained.
MR. CLARK: Okay.
BY MR. CLARK:
Q The average wholesale price, sir, who is it that you testified sets the average wholesale price?
A The manufacturer or, you know, basically, the labelers.
Q Okay. Can the average wholesale price be adjusted

or manipulated one way or the other?
A Once it's set?
Q Once it's set.
A No. It can only be changed by the manufacturer or the labeler.
Q Okay. The only way that the average wholesale price can be changed is by the, who, the manufacturer or the labeler?
A Correct.
Q Pharmacies can play no role in manipulating the average wholesale price?
A Of the actual average wholesale price, no.
Q Okay. Sir, you worked at Freedom Pharmaceuticals. Is that correct?
A Correct.
Q From February of 2013 until September of 2015, I think is what your --
A That looks correct, yes.
Q Is that correct? What was Freedom Pharmaceuticals?
A They were a wholesaler of bulk chemicals. They repacked bulk chemicals and sold them to compounding pharmacies around the country.
Q And what did you do at Freedom Pharmaceuticals?
A I taught a billing class was my prior responsibility where we went through the different PBMs and their manuals and

the dos and the don'ts on compounding billing and how to teach pharmacies to correctly bill compounds.

Q Are you aware that last month Freedom Pharmaceuticals settled with the United States of America for doing just what you've said cannot be done, that is, teaching pharmacy customers how to submit false and inflated compound prescriptions to inflate artificially the average wholesale price?

MR. THOMAS: Objection, Your Honor. We're talking about another case, I think it's unfair to present this to this witness.

THE COURT: Okay. I mean, you know, they -- okay. So, Freedom Pharmaceuticals apparently entered some agreement with the United States, you know, agreement with the United States. Is that right, Mr. Clark?

MR. CLARK: Yes, sir. I'll be happy to show him and ask him --

THE COURT: Does the settlement agreement say that the defendant neither admits or denies? It usually does, but, I mean.

MR. CLARK: It does. It lists the United States' contention, then it lists what Freedom Pharmaceuticals paid.

THE COURT: Does it say whether Freedom Pharmaceutical admits or denies the allegations?

MR. CLARK: I think it states -- I don't believe it

says denies I'll say. I can tell you the exact language.

THE COURT: I don't know. I mean, I'm not sure that's here nor there. Let me tell you what I'm interested in about this average wholesale price and how it's set. For instance, any given drug is, I guess, there are a lot of cases where some manufacturer has a monopoly, they are the only source of this drug. Right?

THE WITNESS: When it's a brand name drug, yes, there is no generics.

THE COURT: Wait a minute. That's different. That's a patent. Let's talk about, you know, let's talk about the underlying, the underlying chemicals that I'm using Pfizer has to pay for in order to manufacture Lipitor. We keep talking about Lipitor, okay. How many manufacturers in the world are there that manufacture those components of Lipitor, just you may need to guess, I mean?

THE WITNESS: The components of Lipitor might be only made by Pfizer.

THE COURT: Okay. Maybe I don't -- here's my question. I'm wondering, the average wholesale price, I'm in my mind sort of analogizing it to the price of a stock on the stock exchange where there are literally thousands or millions of people feeding into the marketplace for that stock. Well, that's -- that can be manipulated, but it's hard, because, I mean, there are so many individual decisions being made. And

that's why we have confidence in the stock market. Well, some of us have confidence in the stock market. Because we are assuming that any individual player is probably going to be incapable or close to incapable of meaningful, meaningfully manipulating, you know, the price of its own stock.

Now, there would be exceptions to that. I mean, you might be able to find a publicly traded company that could convince enough of its insider employees to go, hey, our stock is only worth 50 bucks on the market, go buy it for 100 bucks because that will have the affect of driving up the stock. But, look, that's hard to do. And it takes a lot of money and most people just -- I mean, that's why we have confidence in the stock market. Is that a fair analogy to something called the average wholesale price? Are there enough players in the market to create that sort of assurance that it's hard to manipulate this price?

THE WITNESS: I think that the best analogy is an example. So, let's take a drug, a bulk chemical called Ketoprofen. And let's say there is 14 different suppliers of Ketoprofen out there.

THE COURT: In the world? In the whole world?

THE WITNESS: In the whole world.

THE COURT: Okay. Now, that's not many. And, I mean --

THE WITNESS: That's not.

THE COURT: They could -- 14 manufacturers, if they wanted to probably could conspire to manipulate the price of their product --

THE WITNESS: Well, what happens is that, you know, if I'm a pharmacy, I'm buying Ketoprofen, I have 14 suppliers to choose from, the AWP is normally $100 and there are some that will be $98, there is going to some that's $103. A new company comes on to the market and they set their AWP at $110.

THE COURT: Okay.

THE WITNESS: They can just set it there. They can set it at $3,000, wherever they want to put it.

THE COURT: But in the United States at least antitrust laws would affirmatively prohibit those manufacturers from surreptitiously agreeing to fix a price. We call that price fixing. It gets prosecuted all of the time.

THE WITNESS: Correct. And if you place it at $150 and your purchase price is the same as everybody else, you know, give it six months or so and everybody else is going to creep up to your $150 AWP price. It actually drives AWP up.

THE COURT: Okay. I can't even remember how I got off on this, but, okay. Go ahead, Mr. Clark.

MR. CLARK: Thank you, sir.

BY MR. CLARK:

Q Getting back to whether a pharmaceutical or a

pharmacy can artificially drive up the average wholesale price. Is it your testimony that Freedom, for example, does not have the ability to establish an average wholesale price for let's say Fluticasone?

A They absolutely do. They would set -- Freedom, PCCA, Spectrum any of the chemical companies out there are going to set the AWP.

Q Right.

THE COURT: Is there competition among the companies to establish the AWP or, I mean, do they just -- I mean, can they dictate, I mean, that --

THE WITNESS: I don't know if I would call it competition. It's just they're allowed to set the AWP.

BY MR. CLARK:

Q And Freedom was the company that you worked for. Correct?

A Correct.

Q Was Freedom setting the AWP?

A For their particular chemicals, yes.

Q Was Fluticasone Propionate a Freedom chemical?

A Yes.

Q What is the CPS or CPCSI division at Freedom?

A That was the class I taught on compound billing.

Q So, it had an operating division of CPCSI. Who was the head of that?

A That was me.
Q Now, let me --
A And eventually my partner, Chris Gruber.
Q Let me show this sentence and tell me if you agree with this. Through its operating division CPCSI, and that was you. Correct? Through its operating division, CPCSI --
A Yes.
Q -- Freedom taught its pharmacy customers how to submit false and inflated compound prescription claims to maximize reimbursement from federal health care programs, how to manipulate the usual and customary price in order to obtain reimbursement based upon the AWP, and how to alter compound prescriptions to obtain approval after the claims had been initially rejected. Now, that's what the United States alleged Freedom did.

THE COURT: Are you reading -- what is this, is this the settlement agreement?

MR. CLARK: This is the signed settlement agreement, yes, sir, Your Honor, between the now parent company of Freedom, Fagron.

BY MR. CLARK:
Q Were you aware that Fagron is the now parent company of Freedom Pharmaceuticals?
A Fagron, yes.
Q I apologize for mispronouncing it. Just so we're

fair. It does state in answer to Judge Mattice's, this is neither an admission of liability by the company or concession by the United States that its claims are not well founded. That was part of the claim that the United States brought?

A And I would --

Q Artificially driving up the average wholesale price. Correct?

A I would completely utterly 100 percent disagree with this statement.

Q So, you disagree that that happened. Did you know or had anyone told you that the company agreed to pay 22.05 million dollars to the United States as a result of those allegations to settle this claim?

A I did read that in the news.

Q Okay. So, while you disagree with it, you agree that the company you worked for paid 22.05 million dollars to settle a claim that you were teaching people how to submit false and inflated compounded prescription claims to maximize reimbursement from federal health care programs?

MR. THOMAS: Objection, Your Honor. That's completely misleading. This is a standard civil settlement agreement and a couple of pages back there is an express provision that no one admits any liability.

THE COURT: Well, I think we just read that, I mean.

MR. CLARK: I just read it.

MR. THOMAS: Yes, sir.

THE COURT: He just read it, nobody admits or denies. That's what every settlement agreement says. So, I mean, you know, I don't really know what the relevance is. I mean, I understand that's what the government's contention was in that particular sentence. You know, Fagron, the successor to Freedom says, hey, look, we'll give you 22 million to go away. We don't, you know -- I get that. I've dealt with, I can't remember, I don't know how many settlement agreements I've not only dealt with but drafted. You know, probably a very limited relevance in this trial.

BY MR. CLARK:

Q But you agree --

MR. WALDEN: Can we get a case number?

MR. CLARK: I'll introduce it into evidence.

THE COURT: Why don't we do that? It is what it is. Come look at it, Mr. Walden. It's a settlement agreement.

MR. CLARK: It's a settlement agreement. It's signed by the --

MR. WALDEN: I don't know even the time period that this allegedly took place.

THE COURT: I don't either.

MR. WALDEN: I would object based upon --

THE COURT: I tell you what. Why don't we take -- let's take about a 10-minute recess and you can show defense

counsel what you got here, you know. And, again, let's not pay too much -- I mean, it was apparently an action by the United States against, what, Fagron, the successor company, and it was settled, you know. And, you know, so, that is what it is. I mean, the Court is extraordinarily familiar with how all of this goes, done it hundred times.

All right. Let's take about a 10 or 15-minute recess.

(Short recess.)

THE COURT: All right. Ready to proceed, Mr. Clark?

MS. MAIO: Your Honor, I apologize. I have two brief matters before Judge Lee at 4:00, if I may be excused?

THE COURT: You got your co-counsel here, if you want to leave, that's fine.

MS. MAIO: Yes, sir.

THE COURT: Thanks, Ms. Maio.

MR. CLARK: May I proceed, Your Honor?

THE COURT: Yeah. Go ahead.

BY MR. CLARK:

Q Sir, there was a question about the date for which, the time period this activity alleged in the other matter occurred. I'll show you Page 4, from January, 2012 through December, 2016. And, again, your time at Freedom Pharmaceutical is wholly captured in that time period, is it not, sir?

A Correct.
Q And I understand your testimony today is that you did not teach your pharmacies how to engage in that behavior and you state that pharmacies cannot artificially inflate the average wholesale price. But you would agree with me that the company you worked for paid 22.05 million dollars in response to an allegation that it did exactly that?
THE COURT: Is it the company he worked for or the successor to the company he worked for?
MR. CLARK: The successor company paid it, but it was based upon conduct of the company he worked for under the division that he stated he was the head of, Your Honor.
THE COURT: Okay.
BY MR. CLARK:
Q You'd --
A Correct to your statement.
Q Okay. Now, you were asked by Mr. Walden and I believe you said you met with Mr. Walden as well as counsel for Mr. Wilkerson. Is that correct?
A By, I've had phone conversations, and it's Zack.
Q Okay. How many times did you speak with Mr. Walden in preparation for your testimony today?
A I really don't know the count, five to 10 times, maybe.
Q How many times did you speak with Mr. Wilkerson's

counsel?
A Probably more, 10 to 20 times.
Q Have you ever testified as a witness on behalf of counsel for Mr. Wilkerson before in any other court?
A No, sir.
Q Okay. How much are you being paid by Mr. Wilkerson for your testimony today?
A There is a flat fee and a per hour contract that we had an attorney create for us.
Q And the flat fee is how much, sir, Mr. Wilkerson's paying you?
A If I recall it's $3,000.
Q And then per hour for your testimony, sir, is how much?
A I haven't looked at it in a long time. I think it's around $400 or something.
Q Is it $400 per hour, you're not aware?
A Ballpark. I would have to review it to remember.
Q Are you also being paid by Michael Chatfield for testifying here today, that's the client represented by Zack Walden?
A No, sir.
Q Are you being paid by any other defendants?
A No, sir.
Q Now, you were asked by Mr. Wilkerson's attorney as

to whether or not that there was some confusion back in 2014 as to whether Tricare was a government insurance plan. Do you recall that? Or a government benefits plan.

A Yes.

Q Right. In truth, just so we all know, there was no confusion, was there, sir?

A Tricare is a plan and they utilized Express Scripts to administer the prescription benefit. That's my understanding.

Q But there was no confusion among the pharmacies with respect to whether or not that Tricare was a government program that relied on federal funds, was there, sir?

A I don't believe so.

Q Okay. You've testified about your knowledge of the ESI PBM provider manual from 2014. Correct?

A Correct.

Q Were you aware that on Page 111 it specifically tells the pharmacy that Tricare involves federal funds. Were you aware that that was in there?

A Correct. Yes.

Q Just so we're clear, there was no cloudiness or murkiness or confusion with respect to the pharmacies as to whether or not that Tricare was a government benefit program, was it, sir?

A If they read the manual, correct, yes.

Q All right. And they are bound by the manual. Is that correct?
A Contractually, yes, it's incorporated in the contract that they sign.
Q The PBM is also bound by the manual, are they not, sir?
A Yes, they are.
Q Sir, you stated that the process for submitting compounded prescriptions to insurance companies for reimbursement is a 100 percent transparent process. That was your -- that was your phrase that you used on direct examination, wasn't it, sir?
A Yes, it is.
Q And you agree with that, do you not?
A Yes. After 2011, when you can transmit every ingredient in the compound, as long as they're submitting every ingredient in the compound, which they're required to by per the manual, it's transparent.
Q Right. So, certainly, given that transparency, it's never okay for a pharmacy to submit a fake claim for a patient that doesn't exist, for a prescription that's not needed simply to see how much the PBM is going to pay for that claim, is it, sir?
A For the narrow definition you have there, correct.
Q Well, is there any situation in which you contend

it's okay to submit a fake claim under this 100 percent transparent framework?

A I think there are times when, you know, a pharmacy when you bill a claim and it's been rejected, and it says, you know, two of the eight ingredients are not covered, could a pharmacy, you know, try and figure out before they call the physician what is covered, you know, substitute a different drug, send it off to the insurance, oh, it's covered, okay, let me call the doctor and get the authorization to make that switch. To me, that makes absolute sense.

Q Would you advise the pharmacies that pay you for consulting to submit these fake claims?

A I would not call them a fake claim. But would I advise them, you know, the alternative is any time you have a rejected claim, you've got to pick up the phone and just call the doctor and say, you know, it's not covered, what would you like me to try next.

Q But it's never okay to submit a fake claim simply to see how much the reimbursement is, is it, sir?

A I don't know why you would even do that.

Q Exactly. Because it's never okay?

A Well, I think that you could just take the -- you know the AWP of each ingredient. You could take the quantities. You could just do the math yourself and you know what that claim is going to transmit and bill at. There is no

reason to submit a claim.
Q Fair enough. Now, sir, you were asked about whether or not individual customers of these medications are told how much their insurance company is going to be billed for the drugs. Do you remember those questions?
A Yes, I do.
Q And you stated you believed that the marketers were prohibited from giving that information. Is that correct?
A I don't know that they're prohibited. I just, I don't know that it's even possible for them to give them that information.
Q Have you reviewed the testimony of Brian Kurtz, that's Wayne Wilkerson's business partner?
A No, I have not.
Q So, are you aware that he testified that it was Top Tier's policy to disclose the cost of the medications to the customers?
A I was not aware of that.
Q Okay. Getting back to the questions that were asked by Mr. Walden. You were asked regarding whether or not that there were any specific override codes. You have no way of knowing whether any of the dates on those prescriptions are legitimate and truthful dates, do you, sir?
A I don't know what you mean.
Q In other words, if a prescriber and someone at the

pharmacy were backdating the prescriptions, you couldn't look at the piece of paper and tell that, could you, sir?

A If they entered all of the information and it had the fields for the written date, the submit date, and the dispense date, you could tell from that information.

Q You could tell whether or not that the date written by the health care provider on the prescription was backdated or whether it was accurate?

A You can't tell that. Right.

Q There is no way to tell that, is there, sir?

A Right.

Q Right. There are no formularies for compounded products, are there?

A No. There are just limits, edits, you know, caps.

Q Is it wrong to give an inducement to the patient to get the patient to ask for a compounded medication?

A I don't know.

Q Have you ever recommended that any of the pharmacies that pay you for consulting advice do that?

A No.

Q Would you ever recommend that they do that?

A No, I would not.

Q Because the demand is supposed to create the compounding, the compounding is not supposed to create the demand. Isn't that right, sir?

A That's one way to phrase it I would imagine.
Q Is it accurate?
A For the most part.
Q What part of it do you disagree with, sir?
A Well, a pharmacy in and of itself creates demand for prescriptions.
Q Have you reviewed any -- well, obviously, you did review prescriptions in this case, because you were, you were shown a prescription for James Allen by Mr. Walden. Do you recall seeing this prescription?
A Yes.
Q Okay. Look at this general wellness pill. That's coenzyme Q-10, 100 milligrams, that's CoQ-10. Isn't it, sir?
A Correct.
MR. WALDEN: Your Honor, I'm going to object. I don't believe I actually showed this prescription. Can you show me the date for it?
MR. CLARK: It's a date of 11/26/2014.
MR. WALDEN: I did not show that prescription.
BY MR. CLARK:
Q Let me show you this prescription. You were shown some billing information with respect to James Allen. Have you seen a prescription --
MR. WALDEN: Your Honor, I'm going to object to the mischaracterization. I showed him billing information for

Jacob Burgess.

MR. CLARK: I apologize.

BY MR. CLARK:

Q This is Government's Exhibit 1315. You've seen prescription forms like this, have you not?

A Correct.

Q Okay. Let's look at the general wellness tablet, this is Co Q-10. Correct? What's that for?

A It's, I can't remember, but it's just a wellness, you know, like a vitamin.

Q And I can buy that at Wal-Mart, can't I, sir?

A You can.

Q And --

A Lipoic acid.

Q Lipoic acid. What's that, sir?

A Same thing it's just, you know, a vitamin.

Q It's an aerobic metabolite vitamin?

A Right.

Q I can buy that at Wal-Mart, can't I, sir?

MR. WALDEN: Your Honor, I'm going to object. I believe this line of questioning is outside of the scope of direct examination.

THE COURT: Where are we heading with this, Mr. Clark?

MR. CLARK: Your Honor, he's the one who brought up the pricing for the compounded products. And I was simply going to point out that a general wellness tablet which contains products that I could buy at Wal-Mart was billed for over $5,000.

THE COURT: Well, and, I mean, we've talked a lot about that. I don't know. I mean, I'll let you go into it. I mean, but, you know. I really -- yeah. I'm having trouble fitting this in that the creams that are at issue in this case seem to me to cost a lot of money. I mean, I'm still not totally clear. I mean, I've listened through many witnesses, average wholesale price thing, and all of that. And, I mean, obviously, at a certain period of time, there seemed to be -- well, I don't know how you put it. I'm going to call it a big loophole in the system for compounded drugs. I mean, I've heard testimony that over time the insurance companies themselves and the government have sought to close those loopholes, but, you know, if you can enlighten me on that, that's -- but, I mean, I've listened to many witnesses, I'm still a little bit confused.

MR. CLARK: Yes, sir.

BY MR. CLARK:

Q Sir, the last question I'm going to ask about this. Would you agree with me that all three of these ingredients are common ingredients that I can buy over the counter at

any --
A Individually, yes, you could.
Q That is correct. I could take them all together in those doses, could I not, sir?
A I'm not sure about the lipoic acid, but, yes, for sure.
Q Okay. And it would not cost -- well, you bought -- how much would you expect for me to pay at Walmart for Co Q-10 lipoic acid and Vitamin D3?
A Buy them separately, count of 30 each, who knows, 10 to $20, $30 each.
Q That's correct. And the industry which you were a part of at Freedom Pharmaceuticals found a way to put them together and sell them for in excess of $5,000. Is that correct, sir?
A Well, if a physician wrote for this, and you filled it with the bulk chemicals, and the AWP was entered correctly, it would price out and be covered if it was a formulary drug.
Q I understand you testified that there was no discrepancy code for a marketer to be prescribed a medication himself and get commissions on his own creams. Is that something you would ever advise the pharmacies that pay you for consulting to do?
A I don't know that I would advise them that.
Q Okay. Is there a limit to how much you think it

would be acceptable for the marketer to make off of just his own creams?
A I don't know.
Q What if the patient made over $100,000 just for getting his own cream, is that an issue that would be relevant from a PBM standpoint?
A I would imagine a PBM would want to audit the claims.
Q Because it would be relevant?
A Because they would, they would have a concern, I would imagine.
MR. CLARK: May I have just a moment, Your Honor?
THE COURT: Yes.
(Brief pause.)
MR. CLARK: Your Honor, that's all of the questions I have.
THE COURT: Redirect? Mr. Thomas.

REDIRECT EXAMINATION

BY MR. THOMAS:
Q Mr. Newkirk, I'm going to ask you a couple of follow-up questions to address the matters that Mr. Clark brought on cross-examination. I'll give you just a minute to read that. I'm sure you know what it says, but I'll give you just a second to take a look at all of it. I'm going to ask you a question or two about it.

A Okay.
Q From my notes, Mr. Newkirk, you had stated that under Florida state law it is illegal, correct, illegal for a pharmacy to not collect copayments from Medicaid patients. Is that correct?
A That's the way I've read it, to waive a copay, to waive copayments.
Q To your understanding, does that Florida state Medicaid law apply to any other state?
A No.
Q To your understanding, does that provision apply to any other payor even in Florida?
A It's under Medicaid. So, I don't think so. I don't know.
Q Florida Medicaid?
A Correct.
Q Mr. Newkirk, are you aware, is there a statute applicable in the state of Tennessee that prohibits anyone from collecting a copay?
A I'm not aware of any statute.
Q You're not aware of anything that applies underneath Tennessee law. Correct?
A Correct.
Q Mr. Newkirk, you'll recall Mr. Clark's questions of you regarding whether or not that the bulk materials that go

into compounds are FDA approved. Correct?
A Correct.
Q Then some concerns as to the safety and efficacy of those compounds if in fact they're not FDA approved. Do you recall that testimony?
A Yes, I do. Yes.
Q Just laying a little predicate. Mr. Newkirk, have you ever seen an instance where a medication that standing alone would be FDA approved, say, for instance, Gabapentin which in Neurontin, which would also be included in a compound?
A Yes.
Q So, Gabapentin standing alone would be FDA approved, correct, but put into a compound loses that FDA approval. Correct?
A As soon as it's altered, if it's a capsule, as soon as you open that capsule and you incorporate it into anything else, it is now a non-FDA approved drug.
Q Because it was mixed with other matters and it's broken out of its original container that would be consumed by the patient. Correct?
A Correct.
Q But the Gabapentin is FDA approved. Correct?
A Yes.
Q For safety and efficacy?

A The tablet or capsule, yes, it is FDA approved.
Q And the reason that the FDA approval goes away is because it's put into a compound with other medications?
A Correct.
Q That doesn't make it any less safe or efficacious, does it?
A It does not.
THE COURT: Well, let me ask about that. And I have wondered about that. And I do understand what you're saying, Mr. Thomas, but, again, this probably displays my ignorance of chemistry. But, I mean, just because a substance is FDA approved, does that necessarily mean that when it is combined, mixed with other FDA approved substances that there is not a way that they can be dangerously mixed in a way that it would harm or even kill a human being?
THE WITNESS: Yes.
THE COURT: So, you've got to be careful with this stuff FDA approved or not?
THE WITNESS: Absolutely.
THE COURT: About mix and match?
THE WITNESS: You're still dealing with drugs.
THE COURT: Okay. And a bad mixture, you know, accidentally or not, could have potentially lethal consequences. Right?
THE WITNESS: Absolutely.

THE COURT: All right. Go ahead.
BY MR. THOMAS:
Q And to follow up on that question, that could be whether the drugs are compounded or they're completely separate. There may very well be a completely separate FDA medication that if taken at the same time with let's say Gabapentin could be injurious to a patient. Correct?
A Correct.
Q Whether they're taken separately at the same time or they're mixed together in a compound taken at the same time?
A Correct.
THE COURT: And I presume that's the reason, for instance, when I go to a physician, any physician, or a pharmacist, they want to know what all of the medications I'm taking because they want to make sure that, oh, gosh, we're sorry, Judge, we thought this would help you, but, instead, it killed you or explain, they'd explain it to my widow at that point. Right?
THE WITNESS: Right. Correct.
BY MR. THOMAS:
Q Classic screening for drug interactions. Correct?
A Correct.
Q Responsibility of the physician. Correct?
A Correct.
Q And if the pharmacist sees it and notices that it's

a bad interaction, it is the responsibility of the pharmacist to stop right there and not just fill the prescription knowing full well it doesn't match what's in the Physician Desk Reference, right, and call the doctor?

A Correct.

Q You recall Mr. Clark asked you several questions regarding whether there is or should be or could be or a requirement to sort of have a fail first for an FDA approved medication before moving into compounding. Do you remember those questions?

A Have a failed?

Q Fail first. Meaning, from my notes, Mr. Clark asked you, wouldn't it make sense, wouldn't it be more efficacious and more safe to utilize an FDA approved medication before or instead of a compound medication.

A Correct.

Q Do you recall that testimony?

A I do.

Q Is there any requirement in fact prior to either prescribing a compound or filling and dispensing a compound that there must be the use of an FDA approved medication first?

A Not that I'm aware of. There would have to be a prior authorization reject, you know, must try FDA approved drug first.

Q And that's how it would be handled, correct, through a prior authorization?
A Correct.
Q That if someone sent in a request for a compound, the PBM, knowing that there hadn't been an earlier FDA approved drug to be utilized, would reject the claim. Correct?
A If that's what they required.
Q Because that's the prior authorization?
A Exactly.
Q And it's up to the PBM to set or not. Correct?
A Correct.
Q The nature of the relationship, and we've gone over this, but after cross-examination I feel like I need to go back over it and clear it up. The relationship between the pharmacy and the PBM is contractual. Correct?
A Correct.
Q The pharmacy chooses the PBM and the PBM chooses the pharmacy. Right?
A Yes. They both have to sign the contract.
Q The pharmacy essentially agrees to the PBM requirements whether it be contractual or in the manual in order to be able to stay in network, correct, to be a participating pharmacy?
A To participate, yes, you must sign.

Q In your experience, over 30 years, to the extent that a pharmacy is non-compliant with a provision inside of that PBM contract or inside of the PBM manual, is that a breach of contract or is it fraud?
A It could be a discrepancy.
Q Or a discrepancy?
A Right. I don't know that it would constitute fraud if you, you know, fill a prescription take one daily and you fill 90 as a 30 day supply, is that fraud? I would say no, it's a clerical error. It's a mistake. It's a billing error and it's going to be recouped on audit.
Q And if the pharmacy has operations that are non-compliant, not within the guidelines of the manual, not within the guidelines of the contract, the PBM does an audit, makes that determination of non-compliant, the claims, the individual claims on a one by one basis are deemed to be discrepant. Correct?
A Correct.
Q Because the pharmacy was in non-compliance with the manual. Correct?
A Correct.
Q What's the remedy? What does the PBM do?
A It's a recoupment for the claims that are discrepant.
Q So, the remedy is civil, right, it's a clawback of

the money?
A It is a clawback and typically they'll take it off of future checks.
Q It doesn't generate a criminal fraud action. Correct?
MR. CLARK: Your Honor, please --
THE COURT: Yeah. Let's talk about that, because, I mean, you know, that's been sort of an undercurrent through these entire proceedings. I mean, I get it. I think that -- I mean, obviously, the government thinks bringing this as a criminal action is completely appropriate and so forth. I suspect every single defendant and their counsel would argue that, you know, this, at best, is a regulatory matter, if not just a private contractual matter, Judge. And as a matter of public policy, you know, the criminal law is a poor enforcement mechanism for what's basically a regulatory or contractual matter. I get that. Those are public policy decisions that are above the pay grade of everybody in this courtroom, including me, and I do understand that. But, I mean, I don't intend to delve into that in my decision about this case. I intend to hold the government to its burden of proof beyond a reasonable doubt. So, let's just move beyond that.
MR. THOMAS: Yes, sir. My only post script on that is I was responding when Mr. Clark said would that be fraud.

THE COURT: Yeah.

MR. THOMAS: I'm compelled to redirect.

THE COURT: I mean, and your questions, I'm criticizing either one of you, but your questions themselves, you are two ships passing in the night about how matters like this should be handled. I think we can all agree with that.

MR. THOMAS: Yes, sir.

THE COURT: Okay.

MR. THOMAS: I'll move on.

BY MR. THOMAS:

Q Mr. Newkirk, there was quite a bit of testimony on cross-examination with Mr. Clark regarding, on the requirements of copays. Those copay requirements that the PBMs impose on the pharmacies. That's not imposed upon the marketing agents. Correct?

A Correct.

Q It's imposed upon the pharmacies?

A Correct.

Q The pharmacies are responsible for collecting the copays?

A Correct.

Q Mr. Newkirk, I'm asking the deputy to hand you a document that is a business record that was obtained from Willow Pharmacy. I'm going to ask you to take a look at it and then I'll hand it to opposing counsel. I'm going to have

it marked and try to get it into evidence here. I'll give you a minute to review it.

(Brief pause.)

A Okay. I've briefly reviewed them.

MR. THOMAS: If I can get that back from you.

THE COURT: Can I ask you, Mr. Thomas, in just a moment, is this the first time you've disclosed this document to the government, whatever it is? I don't even know what it is.

MR. THOMAS: I think that it is.

THE COURT: All right. If that's the case, here's the only thing I'm going to say. I'd like to take a 10-minute at least break to let the government review it.

MR. THOMAS: Yes, sir.

THE COURT: I have no idea what that is, but I suspect that I'm going to be encountering an objection of some sort. I'd like everybody to take a look at it and think about what their position is on this.

MR. THOMAS: Yes, sir.

THE COURT: So, let's take a five, 10-minute recess and we'll reconvene.

(Short recess.)

THE COURT: All right. Let's see, Mr. Thomas. You have a document that you're waving around up there.

MR. THOMAS: Thank you, Your Honor.

THE COURT: Is this the letter?

MR. THOMAS: Yes, sir. We've got it marked as Wilkerson No. 6.

THE COURT: Okay.

MR. THOMAS: It's covered up, but these are government numbers that came in through --

THE COURT: Okay. You got these from the government?

MR. THOMAS: Yes, sir.

THE COURT: Okay.

MR. THOMAS: We would contend that's a business record. We've got a stipulation.

THE COURT: Okay.

MR. CLARK: Your Honor, if I could make my objection. We did --

THE COURT: I didn't say you had to have an objection, I just anticipated one.

MR. CLARK: I do. And here's the objection, Your Honor. Simply because something is a business record doesn't mean it's not susceptible to other hearsay rules. There can be hearsay within an authentic business record. This is a letter written by an individual who apparently was representing Willow Pharmacy pursuant to some audit. It's being offered for the truth of what that individual states and it is his opinion that a particular --

THE COURT: Whose opinion?

MR. CLARK: The opinion of the author of this letter, someone named Richard Quadrino that a particular copay amount is covered by a certain Affordable Medical Solutions benefit program.

THE COURT: Okay.

MR. CLARK: And, therefore, is not susceptible to the audit. That's my understanding based upon my conversation with Mr. Thomas why it's being offered. It's being offered to show that Willow, in essence, was allowed to eat anything other than $15 under this particular health care benefit or prescription benefit plan.

THE COURT: Okay. It's a legal opinion as to an interpretation of the contract?

MR. CLARK: Absolutely. And that is my objection, because if we're going to get into that, then I think there is a whole host of other things that we can get into such as one of the prescriptions referenced here in this audit is Emilio Hernandez's prescription who was one of the ones that Mr. Hindmon and Mr. Montgomery went and paid Dawn Montgomery, not Dawn Montgomery, paid Maria Valadez cash for so the prescription, so that copay was actually paid. And I think that the Court has already stated that the Court didn't think this was a particularly relevant issue anyway when I tried to get into it with Mr. Newkirk, so I moved on. And so, for

those reasons I would object. It's a statement of Richard Quadrino being offered for the proof of it. And simply because it's in a valid business record does not make it admissible.

THE COURT: Okay. It's hearsay?

MR. CLARK: Yes, sir, Your Honor.

MR. THOMAS: May I respond, Your Honor?

THE COURT: Yes.

MR. THOMAS: We're not bringing it for the truth of the matter asserted. This is an expert in pharmacy compliance. I'm not asking to render an opinion of an attorney as to whether or not Willow was in compliance. I don't represent Willow. I am bringing this merely to respond to the line of questioning from Mr. Clark that came off of the e-mail from Mr. Hindmon that indicated that there is only a $15 patient copay, and Willow Pharmacy eats the rest.

THE COURT: I've already -- and, you know, I don't know if it would become necessary for me -- I have -- well, I explained I'm not sure that the second and third sentence of that Paragraph 3 refer to the copay. Okay. That's what I'm -- I'm still not sure of that, but it may or may not. I consider it at best a marginal issue in the case, tell you the truth. Look, you know, I don't mind admitting this letter, it's just -- I mean, I'm really to the so what.

MR. THOMAS: Yes, sir.

THE COURT: I really do wonder what the relevance of it is, tell you the truth.

MR. THOMAS: Yes, sir.

THE COURT: What is the relevance of this?

MR. THOMAS: The only reason we were bringing this is to address what we consider to be an allegation by Mr. Clark that Mr. Hindmon and Willow Pharmacy were in some manner violating copay law because --

THE COURT: Well, I'll be honest --

MR. THOMAS: -- the pharmacy was eating part of the copay.

THE COURT: Let me make a statement. If that was Mr. Clark's thrust, I don't blame him for making the argument, but he probably has not yet persuaded me of that. So, I mean, that being the case, do we even need to go into this document?

MR. THOMAS: If that's it, Your Honor, I'll withdraw.

THE COURT: Okay. And I'll give you a chance later on, Mr. Clark, if you want to take another crack at it, but not yet. Okay. So, all right. Let's move on.

MR. THOMAS: Thank you, Your Honor.

THE COURT: You know, and, again, ask him whatever you want to about this, I mean, but I think I understand what this is. It's a settlement between the United States government and a successor to a company that, you know, that

Mr. Newkirk used to work for. And, you know, as all of these settlement agreements does, denies liability. You know, the United States asserts claims, okay, fine. It is what it is. There is language in there that is suggestive of -- that the United States believes somehow that Mr. Newkirk is some sort of fraudster. I don't know if you want to ask him that. I suspect that Mr. Newkirk is going to deny in this courtroom that he's a fraudster, you know.

THE WITNESS: Yes.

THE COURT: You can ask him that, but, I mean, why are we spending much time on this? I mean, okay, there was a settlement, you know, as I said, the Court has done a 100 of them, I mean, a settlement is a settlement.

MR. THOMAS: Yes. I'll leave my inquiry to literally one question.

THE COURT: Do you think you're a fraudster, Mr. Newkirk?

THE WITNESS: No, sir.

MR. THOMAS: That will do it for me.

THE COURT: Your answer quite honestly doesn't surprise me.

THE WITNESS: Thank you.

BY MR. THOMAS:

Q Mr. Newkirk, do you recall the question on cross-examination by Mr. Clark regarding Mr. Kurtz's testimony

that patients were told how much the compounded pharmaceuticals would be. Do you recall that testimony?

A Yes.

Q I would like to offer to you that this is the Top Tier sales process, this has been admitted into evidence, I think both by the government and by Mr. Wilkerson, although, this one doesn't have a marking on it. I'd like you to very briefly to yourself read Paragraph 2.

A Okay.

Q Mr. Newkirk, the Top Tier sales process doesn't require telling patients how much their medications are going to cost, it just requires informing patients reasonably of the range of costs to their insurance company of their compound. Correct?

MR. CLARK: Your Honor, please, he has no way of knowing what the Top Tier sales process is. That was not the question. I asked him about whether or not he knew Brian Kurtz testified that they did require their marketers to disclose this information. So, if he wants to say either through this document simply says that --

THE COURT: I really don't even know -- yeah, I mean, I guess the objection is that does Mr. Newkirk have any knowledge of what, you know, of how Top Tier went about conducting it business, if not, you know, I guess it's okay, I mean, you know, but, I mean --

MR. THOMAS: Your Honor, if it's not relevant on redirect, it's also not relevant on cross, and I'm happy with that.

MR. CLARK: Your Honor, my objection wasn't that it wasn't relevant, it was mischaracterizing what the testimony was in the question --

THE COURT: What do you think the testimony was on cross?

MR. CLARK: The testimony that I asked him on cross-examination was whether or not he was aware that Brian Kurtz testified that it was Top Tier's practice to tell individuals how much their insurance company was going to be billed. Now, now, he has been asked, well, wouldn't you agree that Top Tier's practice was to give them a range. Well, he doesn't know. He can say what this document says, but I don't think it's -- I think it's a mischaracterization for this particular witness --

THE COURT: You know, okay. Why don't you just ask him -- do you want to ask him if he thinks it's a better practice or not, you know, which one, I mean, assuming that there is a distinction between the way that Mr. Kurtz carried out his business and the way that Mr. Wilkerson carried out his --

MR. THOMAS: Yes, Your Honor.

THE COURT: I'll be honest, I think that it would be

better practice for the cereal industry in the United States to tell all of the kids that they advertise how much sugar there is and what it's going to do to their teeth and all of that, but I'm not sure we have laws on the books that require that as to what the best practice is, so. Do whatever you want to do with this.

MR. THOMAS: I'll be brief, Your Honor.

THE COURT: Okay.

BY MR. THOMAS:

Q Mr. Newkirk, you'll recall on direct I asked you was there any way for a marketer marketing compounds to know how much the patient's compound is going to cost. My recollection and my notes state that you said, no, there is no way to tell. Correct?

A Correct. There is no way to tell.

Q On cross-examination Mr. Clark said, well, Mr. Kurtz says the opposite, says that sales reps were telling patients all of the time what the prices were. The only reason I'm bringing this is to demonstrate that there is, in fact, documented sales processes of Top Tier that demonstrates that it wasn't a matter as Mr. Kurtz stated that they were telling patients how much their drugs were going to cost, but just demonstrating a range. Does that seem reasonable and appropriate?

A Yes.

Q Thank you. Mr. Newkirk, in the event that a PBM finds non-compliance at a pharmacy for any reason, the analysis is done on a claim by claim basis. Correct?
A Correct.
Q To the extent that a claim is found to be discrepant, there is a recoupment on that one single claim. Correct?
A Correct. There is no extrapolation.
Q Is there any instance where you have ever seen a determination of non-compliance based upon a pharmacy sending in a test claim, a dummy claim, to determine whether or not that a claim will pay, and, if so, how much it will pay?
A I've understood that PBMs have given feedback to pharmacies when they have a claims pattern of submitting claims and reversing them. They could reach out to the pharmacy and ask what is going on, ask them to stop doing that, or conduct an audit, in all likelihood what that is going to lead to is a field audit.
Q Do you recall on cross-examination Mr. Clark asking you questions regarding would you find it to be discrepant in the event that a prescriber had his or her name stamped on a prescription and didn't even realize it. Do you recall that line of questioning?
A Yes, I do.
Q You're familiar with E-prescribing. Correct?

A Correct.
Q With E-prescribing a physician or the nurse practitioner doesn't physically sign anything. Correct?
A Correct.
Q They push a button in an electronic medical record and it generates an E-prescription. Correct?
A Correct. They sign in --
THE COURT: That's different. Come on. Now, that's different from using someone's stamp surreptitiously and the person doesn't know, as long as they know that someone is filing, I mean, you know, it may not be forgery, but, I mean, if a person doesn't know, it's forgery. Right?
MR. THOMAS: Yes, sir.
THE COURT: Okay. That's that.
MR. THOMAS: I'll move on quickly.
BY MR. THOMAS:
Q Is there any way for the pharmacy to know when an E-prescription comes in whether or not that the prescriber had approved it or not?
A No. Other than, you know, typically the prescriber is who can sign into the system to prescribe, you know, the prescriber walks away from the terminal and someone enters a prescription under the prescriber, yes.
Q Do you ever recall in your 30 years of experience having a discrepant claim due to a prescriber stating I didn't

sign that prescription?
A Yes. But not with an electronic prescription. It's pretty much, it's pretty much there.
Q So, it was found to be a discrepant claim because the doctor didn't actually order the medication, somebody else did and the doctor didn't approve it?
A Correct. Or that the doctor doesn't have a record of approving it.
Q What was the remedy in that case, what happened?
A Recoupment of that particular claim.
Q Civilly?
A Correct.
Q Underneath the contract?
A Correct.
Q You'll recall Mr. Clark asking you questions regarding the sufficiency of the physician patient encounter, when the patient was seen or not seen by the doctor. Do you recall that testimony?
A Correct. Yes.
Q In the event that there was a discrepant claim found because there was an insufficient encounter between the doctor and the patient, what would the remedy be?
A Recoupment of that claim.
Q That one single claim?
A That one claim, yes.

Q Just the money?
A Correct.
Q Civilly?
A Correct.
Q Under the contract?
A Correct.
Q You'll recall Mr. Clark asking you on cross-examination that a pharmacist can't unilaterally change a prescription without consulting with the physician. Correct?
A Correct.
Q Is that the same as if the pharmacist is just utilizing a clinical equivalent and swapping out one medication for a clinical equivalent?
A It has to be the same drug. You cannot take two NSAIDS non-steroidal anti-inflammatories and swap one for the other. You need permission from the doctor.
Q Is there any instance when a clinical equivalent can be utilized without contacting the physician?
A Not that I'm aware.
THE COURT: A generic. Right?
THE WITNESS: You could choose if there is five different generics of the same drug, you could choose which generic you choose to dispense.

BY MR. THOMAS:

Q In these matters that we've been talking about, discrepant claims, where the pharmacy submits to the PBM a claim that the PBM finds is not sufficiently compliant to pay, and finds a discrepancy, either not pays or does a recoupment. Correct?

A Correct.

Q To what extent is the marketer responsible for that discrepant claim underneath the PBM manual and the contract?

A I don't know of, you know, any instance where the marketer is in any consideration.

Q It's a responsibility of the pharmacy. Correct?

A The pharmacy and the physician. Correct.

MR. THOMAS: Thank you, sir.

THE COURT: Anything else, Mr. Clark, or any other defendants?

MR. WALDEN: Nothing further from us, Your Honor.

THE COURT: Mr. Clark?

MR. CLARK: Your Honor, I'd like to introduce the prior witness statement of Mr. Newkirk regarding copays that he's been questioned on?

THE COURT: Any objection to that?

MR. THOMAS: No, Your Honor.

THE COURT: Admitted.

(Government's Exhibit 58 was received into

evidence.)

THE COURT: Any questions?

MR. CLARK: No questions, Judge.

THE COURT: May this witness step down and be excused?

MR. THOMAS: Yes, sir.

THE COURT: Thank you, Mr. Newkirk. You're excused. All right.

(Witness excused.)

THE COURT: All right, counsel. Let's talk a little bit about where we go from here. Of course, we're drawing close to 5:00 today. I don't know if there is much else we can do today, but what happens tomorrow morning?

MR. SCHWARTZ: Judge, at this point, at least as to --

THE COURT: Why don't you come to the podium, I can't hear you, Mr. Schwartz.

MR. SCHWARTZ: Yes, sir. At this point, as to Wilkerson, and I believe the rest of the defense, but they can correct me if I'm wrong, I've got a handful of documents that we received in discovery that I want to just admit. And then we don't intend to call Mr. Wilkerson, but I would request --

THE COURT: You do not?

MR. SCHWARTZ: Do not. I would request a just general colloquy that tells all of the defendants that they

have the right to testify if they wish to.

THE COURT: Well, of course, they do, but they -- but, you know, and I tried to give them that today, maybe I need to do it again tomorrow. But they have -- the most important thing they need to know is they have an absolute right not to testify. Of course, they have the right -- it's a waiver of their right not to testify. And they need to know that I am prohibited, that I am prohibited by law from drawing any inferences --

MR. SCHWARTZ: Yes, sir.

THE COURT: -- from their failure to testify. In other words, what you need to know, I'm talking to the defendants, if you choose to testify, fine, you have that right. But if you choose not to testify, I am prohibited by the law to drawing any inference from your, the fact that you chose not to testify. In other words, I am prohibited by law from saying, ah, they must be guilty or else they would have gotten on the stand and told me they were innocent. I can't do that, not in the United States of America.

Okay. What else do I need to say? I mean, that's under the Fifth Amendment, you know, but those, of course, you can testify. I mean, you've heard there is some people that think, you know, the jury wants to hear me say I didn't do it. Okay. Well, and that's fine. And you may think that I want to hear you say you didn't do it. And that may or may not be

true. But what I do know is someone who's done this for many, many, many years, I mean, it's part -- I'm hard wired. It's part of my DNA is that I know I cannot hold it against you in any way, shape, or form if you do not testify. Okay. I cannot even subconsciously think that if they were innocent they would have gotten on the stand and told me, you know. That's just the, that's the law in the United States of America.

Does anybody have any questions? I mean, you know, again, I'm just hard wired to think this. And lawyers that deal in criminal law are hard wired for this, but you need to understand that. And if you do choose to waive your right to remain silent, I suggested the other day, consult carefully with your lawyers, because whatever upside you may think that there may be, I think that your lawyers can tell you they've seen it go wrong, sometimes horribly wrong, you know, on cross-examination. Because I can almost guarantee you if you choose to get on the stand that the government will pull out all of the stops to whatever they can come up with on cross-examination, you know.

So, I don't know how to be any more blunt or specific than that. That's usually -- I usually say it a little bit more eloquently, but maybe people don't get it, you know, so. Is there anything else I can do?

MR. SCHWARTZ: No, sir. I think you did a more than

sufficient job the other day talking to them about their right not to testify, and I just wanted to make sure they all understood they have a right to if they want to.

THE COURT: Absolutely. I mean, they can waive any constitutional right that they have, you know, including the right to free speech and everything else. And tell you the truth, most Americans don't think, we do it every day when we sign employment agreements that prohibit us from, now you work for us, you can't go out and say whatever you really think, you know --

MR. SCHWARTZ: Yes, sir.

THE COURT: -- about that. So, okay. So, tomorrow you want to introduce some documents into evidence?

MR. SCHWARTZ: Yes, sir. Just it will be real quick.

THE COURT: What about other defendants, Mr. Eldridge?

MR. ELDRIDGE: Thank you, Your Honor. On behalf of Michael Chatfield, we have every expectation that we will rest in the morning after Mr. Wilkerson rests. At this point, we do not anticipate any additional evidence on his behalf.

THE COURT: All right.

MR. ELDRIDGE: I don't want to formally rest at this point.

THE COURT: That's fine. I'm not going to ask you

to rest until tomorrow. Mr. O'Shaughnessy?

MR. O'SHAUGHNESSY: I anticipate the same, Your Honor.

THE COURT: That Ms. Nicholson will rest?

MR. O'SHAUGHNESSY: Yes, Your Honor.

THE COURT: All right. Let's see. Who's next?

MR. WHETSEL: Same for Mr. Hindmon, Your Honor.

THE COURT: All right. And last but not least, Mr. Montgomery?

MR. HOBBS: Same for Mr. Montgomery, Your Honor.

THE COURT: Okay. Well, it sounds like that the defense will rest. Now, Mr. Piper, let me ask you. I think you indicated the other day that you anticipated that the government might seek to put on a rebuttal case. Why don't you come to the podium.

MR. PIPER: We do, Your Honor. There is an issue that's arisen that I've informed defense counsel of.

THE COURT: Why don't you enlighten me.

MR. PIPER: I am going to, Your Honor. Thank you. We spoke to Noah Bowling and Luke Bowling, this is the Finley Stadium incident, yesterday. They're both represented by Bryan Hoss.

THE COURT: Okay.

MR. PIPER: We spoke to Noah Bowling for five minutes. Then Luke did not testify last time, as the Court

may recall, only Noah did. And we were going to call Luke Bowling for the issue of whether the five scripts were given to Mr. Chatfield there at Finley Stadium.

THE COURT: Okay.

MR. PIPER: Or whether they picked up three --

THE COURT: This is the issue that we encountered the other afternoon where Mr. Clark and perhaps I was too hasty, Mr. Clark, I said do you really think that Ms. Chatfield was not there in the parking lot at Hamilton Place, and just this is a complete fabrication. And I didn't give you a chance to answer. I'm taking it from what Mr. Piper, you do think that was a complete fabrication. Right?

MR. CLARK: Yes, sir, Your Honor.

MR. PIPER: Well, we --

THE COURT: I mean, I guess, there could be ways to reconcile these two stories.

MR. PIPER: There is I'm sure, Your Honor, but the problem is -- let me get to the problem.

THE COURT: Okay.

MR. PIPER: Is that when we talked to Luke Bowling yesterday, we were discussing this with him. And I said have you talked to anybody else, he said no, and he's lived up to our and the Court's admonition on not discussing case with anybody else. And we started to get into the specifics and then Mr. Hoss in about two or three minutes said, oh, by the

way, he has read --

THE COURT: Okay.

MR. PIPER: Judge --

THE COURT: And he was excused, by the way.

MR. PIPER: He never testified, Luke Bowling.

THE COURT: Oh, oh, oh, okay.

MR. PIPER: Luke Bowling never testified, Your Honor, and I do think that the rule of sequestration would apply to him. And, Judge, I'll be real up front. The three witnesses we were going to call would be probably in this order Luke Bowling, Noah Bowling, and Debbie Foster, who is Natalie Foster Chatfield's mother. She's testified before and Noah has testified before.

THE COURT: Well, now, what does Ms. -- look, maybe I don't understand. Okay. Look, here's the way I recall the testimony from, I guess it was Noah Bowling. We're talking about Finley Stadium. I said, okay, you're in Finley Stadium parking lot, did you just do the papers there on the hood of the car. And I recall that I asked that question and he said, oh, yeah, just -- now, I don't know if I got down to or anybody got down to did you actually sign the papers there and that was the end of it or were the papers just exchanged on, but --

MR. PIPER: Noah is specific about that, Your Honor, during his testimony.

THE COURT: Okay. Is he also specific about whether there was any meeting the next morning about whether or not that anything took place in, as I recall, outside of the men's department of Belk in Hamilton Place parking lot?

MR. PIPER: Dillards, I think, Your Honor.

THE COURT: Okay. Wherever.

MR. PIPER: We did not know that. Mr. Eldridge did not cross-examine on that. We didn't do any direct on that with Noah Bowling. And I understand the defendants' concerns, Your Honor, about this issue as far him reading the Chattanoogan article with respect to what Grayson Fuller Chatfield and Brandon Chatfield said on the stand. As the Court may recall, there was, I think that was last Thursday night when Your Honor threatened to hold the entire courtroom in contempt.

THE COURT: Which, by the way, that threat still exists.

MR. PIPER: Thank you, Your Honor.

THE COURT: Of course, that's the way it does in any of my proceedings. Right?

MR. PIPER: Thank you, Judge.

THE COURT: Okay. All right. Go ahead.

MR. PIPER: But my point is that it was animated, and I think that there was a fairly significant press coverage of that at least from the Chattanoogan. And Luke Bowling has

read that, so.

THE COURT: Okay.

MR. PIPER: That's of concern to us, Your Honor, and in fairness it showed be to the defendants. I do know that when there is a jury trial, the Court always admonishes the jury not to read or watch TV or anything about the case when we take off at night. I don't know that the Court gives that admonition to a defendant, but Mr. Luke Bowling has never testified.

THE COURT: I don't --

MR. PIPER: Judge, we may decide for this reason not to call him. I don't know that, you know. Mr. Noah Bowling testifies to it. Debbie Foster would be our other witness. And, Judge --

THE COURT: You know --

MR. PIPER: -- when I had Debbie Foster on the stand, I was trying to ask her about whether she had a conversation with Ms. Natalie Foster Chatfield and Mr. Eldridge objected, and the Court asked her a question regarding her interaction with her daughter. It's in the transcript, Judge.

THE COURT: Okay. I don't remember. That has been several weeks ago.

MR. PIPER: Yes, sir.

THE COURT: What did I ask her?

MR. PIPER: You said did you lie to help your daughter, protect, cover it up.

THE COURT: Yeah. What did she say?

MR. PIPER: Yes.

THE COURT: Okay. Yeah.

MR. PIPER: And my point is we may decide not to do a rebuttal case, and I understand --

THE COURT: This goes -- as I recall Mr. Eldridge explaining to me, this goes to, what, two or three counts of aggravated identity theft?

MR. PIPER: Four, Your Honor.

THE COURT: Four. Okay. Look. For Mr. Chatfield and every other defendant, every count is important. Okay. Every count is important. I'm certainly not going to do that, but let me just say this, counsel. And, I mean, I'm not there yet. Okay. But depending upon how this plays out, the Court, I may view this case as being a big indictment that for all practical purposes charges one count of conspiracy to commit health care fraud. I'll let you argue whether I should view it that way or not. And that almost every other count, if not, probably this is a gross oversimplification, goes to an overt act or not in furtherance of that conspiracy. I mean, you know, I'm going to let you argue all of that. Okay. But here's what, here's the point I'm trying to make. Hey, if you want to put on a rebuttal case, fine, sounds like there could

be problems one way or the other, but I'm just, you know, no detail is too small when someone's liberty is at stake to overlook, but I'm just giving you the benefit of my thinking about this.

MR. PIPER: Your Honor, we're going to discuss it tonight and make a decision.

THE COURT: Okay. Well, I'll hear from you in the morning. I mean, I'm inclined to probably if you want to go through, but I guess what I'm saying is that's important, but not, it perhaps is not as important as you might imagine in my mind.

MR. PIPER: I understand, Your Honor. I do think that Mr. Eldridge had an objection that he might want --

THE COURT: What would be your objection?

MR. ELDRIDGE: Your Honor, I mean, based upon -- I commend Mr. Piper for disclosing this information about Luke Bowling and his exposure to the testimony of another witness, which is a functional equivalent of a violation of the rule of sequestration.

THE COURT: Yeah, it is.

MR. ELDRIDGE: We will be objecting to his testimony on that basis.

THE COURT: All right. Okay. Well, you know, and your objection will be noted, you know. It may be that I'll take it for what it's worth. And what I've just tried to say

is that, look, it would be wrong of me to have made up my mind about this case, but I think I've tried to tell you how I'm thinking about this case all along. And I suspect that at this juncture, counsel, it's not come as much of a surprise to you that that may be the way I'm thinking about this case about what it's about, what this whole case is about.

MR. ELDRIDGE: And, Your Honor, with regard to the ag identity theft allegations against Mr. Chatfield, I mean, they are serious and we --

THE COURT: Yeah, every criminal --

MR. ELDRIDGE: Because they actually do have a mandatory jail sentence attached to them if he's convicted. And there are two components to those charges. One is what the Court has already identified, I mean, there has to be a predicate.

THE COURT: Yeah.

MR. ELDRIDGE: Without the predicate, we don't even get to whether he improperly used their identity, and the Bowling, Foster testimony has all gone to that component, you know, did he use that identity without their permission.

THE COURT: And, by the way, as I always tell jurors, and I think that I'm supposed to do that in this case, at this juncture, I don't think that I should be considering what possible punishments are for the offenses charged.

MR. ELDRIDGE: And I understand. I probably

shouldn't have said that.

THE COURT: I think I should be deciding whether, you know, I should find the defendants guilty or not guilty of those. And we've still got all of these outstanding issues, you know, of merger, so forth and so on, which are big issues in an indictment like this. I think everybody can agree. I mean, those are going to be important. And I'm going to have to have argument about that.

Let's go beyond tomorrow then. Here's what --

MR. PIPER: Mr. Schwartz had a question, I think.

THE COURT: Yes, sir.

MR. SCHWARTZ: I'm sorry. So, it looks like, it looks like it's anticipated that at least the defense will rest and likely the government may bring a few witnesses.

THE COURT: Or not.

MR. SCHWARTZ: Or not.

THE COURT: And you're going to get some documents in.

MR. SCHWARTZ: Yes, sir, just real basic stuff. Are you going to want to roll into, if after they're done and they rest, are you going to want to roll into closing right away --

THE COURT: No. No. No. Here's what I'd like to do. We've set aside like eight full days. And I'm assuming that you are capturing on this calendar if I call you back for those. Okay.

MR. SCHWARTZ: Yes.

THE COURT: But here's what -- let's just -- this is a good conversation. Let's talk about what happens. I think that the next thing once both sides have rested that we need to turn our attention to is go into what I'm going to refer to, I can't remember, 801(d)(2)(E), *Enright* hearings. And I've said, I understand that there were a lot of objections. I reserved ruling on a lot of them. I admitted a lot of exhibits conditionally, but I need to know now that the dust is settling, okay, what are you serious about, defendants, about me not considering. Get down, what do you really think I should not consider.

Now, I also said the other day I am considering calling witnesses on my own. One reason, one possible witness that I might call on my own is witnesses that go to the *Enright* issues, which, I mean, as Ms. Maio pulled up a case the other day, there is precedent for me to do that in that, so, I mean, I'll need to consider that. I encourage everybody to read that case.

Okay. Beyond that, and assuming I don't call any other witnesses of my own accord, it seems to me that we also need to have the equivalent, I've never done this before, of a charge conference and at least let you know probably by way of some document, maybe a proposed order or something, the standards that I anticipate, the legal standards that I

anticipate applying to each and every count of the indictment and give you an opportunity in something akin to, you know, a Rule 31 charge conference to object or try to convince me to modify the legal standards that I'm going to apply.

Okay. At that point, we need to consider how we're going to make closings, you know. Again, I think somebody has to ask me for written findings of law and conclusions of fact, I mean, findings of fact and conclusions of law. I've always been assuming that someone will ask me for those, but maybe not. I mean, I guess I can just sit here from the bench and declare someone guilty or not guilty of certain counts. And maybe, maybe you and your clients want it that way. I don't know. I really just, I mean, again, this is almost unplowed ground for me. This is only the second criminal bench trial I've had. So, I need to know that as well.

I will assure you even if you don't want formal written findings of fact and conclusions of law that I will take this under advisement and, you know, carefully consider the entire record before I decide upon. So, I guess what I'm saying, in my case, there is going to be extended period of deliberation, not unnecessarily extended, but I'm going -- you would not want to be sitting in this courtroom while I'm trying to decide. Okay. Because, I mean, I may -- it may take me awhile. Okay.

MR. SCHWARTZ: As to that circumstances, the defense

has discussed whether we will request those written findings, and it's my understanding that we are not going to.

THE COURT: You are not? What about the government, does the government have the right to ask for under the rules written findings of fact and conclusions of law?

MR. PIPER: I'm going to have to research that, Judge.

THE COURT: Okay. All right. I need to know that, I mean, you know, and really it's just a matter of what -- you know, in the event, in the event that I find one or more of the defendants guilty of anything, I mean, you know, what goes to the Sixth Circuit. I mean, right?

MR. SCHWARTZ: Yes, sir.

THE COURT: In a jury, in a jury trial all that goes to the Sixth Circuit is the finder of fact verdict and the complete record, you know, and leave it to the sides to figure out --

MR. PIPER: Judge, and we've been in trial, I think, for over the span of two months and two days, we started on September 11th, and it may be helpful for the Court for the parties to brief the factual issues at least that we've called --

THE COURT: I'll probably ask you to do that no matter what. And I'm likely to ask you after you've briefed it to come back for at least half a day or a day and make oral

arguments to me, you know, and tell me, you know, what you think I may have missed, you know, in that. I mean, look, this is critically important. And I hope I've convinced everybody in the courtroom, particularly, including the defendants that I'm taking this deadly serious, I mean, you know, that I fully understand the gravity of, you know, what I'm being asked to do, which is defined, is to make decisions regarding potentially someone's liberty.

You know, depending upon how we do this, I may or may not be around to be, if there is a finding of guilt, the sentencing judge. And, of course, let me just say something else. If I am the sentencing judge another issue will be what the appropriate punishment is. And, of course, I'll have to look at the guidelines and so forth, and so on. But, I mean, this the only reason I mention this, I mean, if there is no statutory mandatory minimum that I'm bound by, I'm reluctant to even go into this, but, I mean, you know. And I don't think I will. There are a range of punishments that could be imposed in the event of a finding of guilt. So, I mean, you know, there is still a lot for us to talk about, I guess is what I'm saying. This is not over yet even though this phase may be over and I'm sure to everyone's relief.

Anything anybody wants to say?

MR. PIPER: 10:00 tomorrow morning, Your Honor?

THE COURT: Yeah, I think, don't I have -- yes, I

have a sentencing at nine, you know. So, yeah, 10:00 tomorrow morning. Anything else we -- yes, sir.

MR. SCHWARTZ: So, after obviously the defense rests and the government puts on their few witnesses, I'm sure we'll have time, what are you looking for, are you going to cut us loose or are you looking for us to have something for you?

THE COURT: Look, I'm inclined to cut you loose for the rest of this week, tell you the truth, but maybe come back next week, when, on Tuesday have we got set aside?

MR. PIPER: Tuesday, Wednesday, and Thursday, Your Honor.

THE COURT: Because we've really got to do that 801(d)(2)(E), the *Enright* hearing. We need to get that under our belt at a minimum. Okay. And then let's go from there, if that is it, okay, then I'll know what the universe of facts I'm dealing with and then we can talk about how we brief this, conduct closing arguments, and what kind of verdict you want from me. Okay?

MR. SCHWARTZ: Yes, sir.

THE COURT: All right. And you need to discuss among yourselves about that verdict, you know. And, I mean, I can understand. That's an important issue, because if, if an appeal is necessary, it's probably going to make a pretty significant difference about what kind of record goes to the Sixth Circuit. Right?

MR. SCHWARTZ: Absolutely.

THE COURT: You know, so, you need to give -- yeah. Okay. Anything else? Mr. Clark.

MR. CLARK: Yes, sir, Your Honor, please, the last exhibit that I introduced that I didn't have a number for for the record is number 58.

THE COURT: As I've admonished you all during the trial, make sure you've got straight with Ms. Capetz what you think is in and not in evidence.

MR. CLARK: I'm sorry, Your Honor. It was number 98. Thank you.

THE COURT: Okay. One final thing. Ms. Andrews, how are the requests for transcript going?

(Off-the-record discussion)

THE COURT: Okay. Have I been clear enough? It sounds like that tomorrow is going to be a relatively short day. And I would say let's then just adjourn for the rest of this week and then come back next week and be prepared for an *Enright* hearing on 801(d)(2)(E) issues. And then we'll discuss what kind of verdict the parties are seeking. And then once I understand that, I'll be in a better position to talk about what sort of closing arguments I'll want. Okay.

MR. SCHWARTZ: One last question. And just for planning purposes especially for Mark and I because we're so far away, given that we expect that the *Enright* hearings will

be concluded next week --

THE COURT: I would think, I mean, I can't imagine those lasting more than a full day, although, I've been surprised before.

MR. SCHWARTZ: I agree with that. We're not going to have to worry about closing next week?

THE COURT: No, I don't think, I don't think so. I'll call you back for that whenever -- and it could be that if you want to delay closings for some period of time until you get transcripts, that will be fine, and I'll reserve -- but I do anticipate that I'll probably ask you for not only written post hearing submissions but oral argument on closings. Okay.

So, let me just, as a practical matter, and I don't know how your clients feel about this, it is probably unlikely that I will render a verdict until after the beginning of the new year sometime. Okay? That's just what I anticipate looking at my calendar for the rest of this year, which is only six weeks, believe it or not, and stuff like that, so.

MR. SCHWARTZ: And I believe after next week the next days we have are December 11 and 12.

THE COURT: Which we may or may not even use those depending upon how it plays out, you know. I mean, if you can get something fine, but if need be and if I want something in writing, and you want transcripts, it may be that we'll just

look into January or something and schedule some new dates. Okay?

MR. SCHWARTZ: Okay.

THE COURT: Does that make sense?

MR. SCHWARTZ: Yes, sir.

THE COURT: Okay. By the way, if what I've sort of off of the top of my head described here doesn't make sense to you after you -- let's talk about it tomorrow morning as well.

MR. ELDRIDGE: Very well, Your Honor. Thank you.

THE COURT: All right. Anything else, anyone?

MR. PIPER: Judge, with the closing, will it be an oral argument situation where the Court is peppering us with questions or will it just be --

THE COURT: Well, let's just -- I mean, you know, what if -- to be as thorough as possible, we've been, I think we've done this, would it make more sense for you to submit written briefs, post hearing briefs to me and then let me read that and read relevant portions of the record and call you in for oral argument. I'll let you make an argument, but I anticipate, you've been in front of me a lot, Mr. Piper, as you know, I'm a pretty active bench most of the time and I may have some questions on that, okay, counsel, what about this, I'm confused about this, illuminate, what do you think about this. Okay?

MR. PIPER: That answers my question, Judge.

THE COURT: Yeah. Okay. Anything else?

MR. ELDRIDGE: No, Your Honor, not at this time.

THE COURT: All right. Everybody have a good pleasant evening. We'll be in recess until 10:00 tomorrow morning.

(Evening recess.)

I, Shannan Andrews, do hereby certify that I reported in machine shorthand the proceedings in the above-styled cause held November 13, 2019, and that this transcript is an accurate record of said proceedings.

s/Shannan Andrews
Shannan Andrews
Official Court Reporter